COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor (804) 367-4456 (Tel)
Richmond, Virginia 23230 (804) 527-4472(Fax)

Tentative Agenda of Meeting
Ad Hoc Committee for Drug Donation Program and Drug Disposal

July 23, 2008

10:00AM

TOPIC	PAGE(S)

Call to Order: Dave Kozera

- Welcome and Introductions
- Reading of emergency evacuation script
- Approval of Agenda

Call for public comment: The Committee will, at this time, receive comments from the public on the establishment of a prescription drug donation program or the issue of drug disposal only.

Review and discussion of draft proposed regulations for a prescription drug donation program 1-7

Review and discussion of the issue of drug disposal to include a review of Oregon's report from the pharmaceutical take back stakeholder group 8-124

Adjourn: The committee will adjourn not later than 3PM

***The Committee will have a working lunch at approximately 12 noon. Discussions regarding drug disposal will begin approximately 1pm.**

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or

3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

B. (For contingent expiration - see Editor's note) Pursuant to a voluntary agreement between a nursing home or a hospital and a pharmacy, drugs may be transferred in accordance with subdivision A 2 between the nursing home or the hospital and the pharmacy for re-dispensing to patients of clinics organized in whole or in part for the delivery of health care services without charge, or to the indigent, free of charge, if the following procedures are satisfied:

1. The physical transfer shall be accomplished by a person authorized to do so by the pharmacy;

2. The person or his authorized representative from whom the prescription medication was obtained shall provide written consent for the donation and such consent shall be maintained on file at the licensed nursing home or hospital;

3. The person's name, prescription number, and any other patient identifying information, shall be obliterated from the packaging prior to removal from the licensed nursing home or hospital;

4. The drug name, strength, and expiration date or beyond-use date shall remain on the medication package label;

5. An inventory list of the drugs shall accompany the drugs being transferred that shall include, but not be limited to, the medication names, strengths, expiration dates, and quantities; and

6. Outdated drugs shall not be transferred and shall be destroyed in accordance with regulations adopted by the Board.

The pharmacist-in-charge at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no product shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured.

B. (For contingent effective date - see Editor's note) The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A2, for the purpose of re-dispensing such drugs to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured.

C. Nothing in this section shall authorize the donation of unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended.

D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the transfer of any prescription or any consumer information regarding the transferred prescription medication pursuant to this section.

Juran, Caroline

From: Board of Pharmacy
Sent: Tuesday, July 15, 2008 12:06 PM
To: 'Colleen Chawla'
Cc: Russell, Scotti
Subject: RE: Virginia Prescription Drug Donation Program

From: Colleen Chawla [mailto:cchawla@celgene.com]
Sent: Tuesday, July 15, 2008 12:13 AM
To: Board of Pharmacy
Subject: Virginia Prescription Drug Donation Program

Per my conversation with Caroline Juran and on behalf of Celgene Corporation, I am writing with regard to the Virginia Prescription Drug Donation Program, enacted by HB 85 (2008). Celgene respectfully requests that the Ad Hoc Committee on Drug Donation Program and the Board of Pharmacy include in the program's regulations language excluding prescription drugs subject to restricted distribution programs from donation or redistribution under the program.

Celgene Corporation manufactures Thalomid® (thalidomide), a unique, extremely active compound, with the potential to cause severe birth defects. In light of the tragedy that occurred several decades ago, it was believed that thalidomide could not be distributed for any use in the United States. Yet, Celgene has researched and developed thalidomide as an effective treatment for patients with leprosy and patients with a form of blood cancer called multiple myeloma.

The federal Food and Drug Administration imposed restricted distribution programs for Thalomid and for another Celgene drug, Revlimid® (lenalidomide) based on its determination that each drug provides a benefit to patients, but absent tight controls and limited access, use poses a significant threat to the public health. The registration (or restricted distribution) programs, the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) for Thalomid and RevAssist® for Revlimid, require that Celgene track each prescription from the licensed prescriber, through the pharmacy, to the patient in order to minimize the risk of fetal exposure. Only licensed prescribers, pharmacies, and patients registered with the S.T.E.P.S. or RevAssist programs are authorized to write, fill, or receive a prescription for these drugs. This enables Celgene to reconcile the medication shipped to pharmacies with what is ultimately dispensed to patients. In addition, it ensures that registered patients receive initial and ongoing education about the risks and necessary precautions associated with these drugs. These risk management programs and explicit directions to patients not to share the drugs are an integral part of the FDA-approved product labeling.

Therefore, Celgene requests that the Virginia Prescription Drug Donation Program regulations prohibit the donation and redistribution of prescription drugs subject to restricted distribution programs. There is precedent for this exemption in other states. Colorado has a cancer-specific drug donation program that excludes products that have restricted distribution programs. (6 CCR 1015-10 §1.3(9)(4); www.cdphe.state.co.us/regulations/preventionservices/101510Cancerdrugrepository.pdf). Arizona has included similar language in their recently posted draft regulations implementing the Arizona Prescription Medication Donation Program. (R4-23-1203(1c); http://www.azsos.gov/Public_Services/Register/2008/23/proposed.pdf). Additionally, the Kansas Board of Pharmacy met last month to discuss pre-draft regulations that also include this exemption.

I very much appreciate your consideration of Celgene's requested exemption. We believe that including

this exemption in the program's regulations will establish important safeguards to protect patients participating in the program. I plan to attend the July 23rd Ad Hoc Committee on Drug Donation Program meeting and look forward to continuing dialogue on this important issue. Please feel free to contact me if you have any questions or if I can provide you with any additional information.

Sincerely,

Colleen Chawla
Manager, State Government Relations
Celgene Corporation
Bus: (510) 339-1693
Cell: (510) 418-2368
Fax: (510) 339-8064
cchawla@celgene.com

DRAFT REGULATIONS FOR ESTABLISHMENT OF A DRUG DONATION PROGRAM

18VAC110-20-10 Definitions

...

"Drug donation site" means a permitted pharmacy that specifically registers with the Virginia Board of Pharmacy for the purpose of receiving or re-dispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

...

18VAC110-20-400. Returning of drugs and devices.

~~A.~~ Drugs may be accepted for return or exchange by any pharmacist or pharmacy for resale in accordance with the provisions of §54.1-3411.1 A of the Code of Virginia. Devices may be accepted for return or exchange provided the device is in the manufacturer's original sealed packaging.

~~B. Any pharmacy accepting drugs returned from nursing homes for the purpose of redispensing to the indigent free of charge shall maintain a copy of a written agreement with the nursing home in accordance with §54.1-3411.1 B of the Code of Virginia and a current policy and procedure manual describing the following:~~

~~1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;~~

~~2. Procedure for determining the suitability and integrity of drugs for redispensing to include assurance that the drugs have been stored according to official compendial standards; and~~

~~3. Procedure for assigning a beyond-use date on redispensed drugs.~~

PART XVII PRESCRIPTION DRUG DONATION PROGRAM

18VAC110-20-740. Drug donation sites.

A. Any pharmacy with a current active pharmacy permit may apply on a form provided by the Board for registration as a drug donation site. A registered drug donation site may receive eligible donated drugs, transfer such donated drugs to another registered drug donation site, or re-dispense the donated drugs in accordance with § 54.1-3411.1 of the Code of Virginia to patients of clinics organized in whole or in part for the delivery of health care services to the indigent. Drugs collected under the drug donation program may not be dispensed to any other patient, sold, or otherwise distributed except as authorized in 18VAC110-20-770 or 18VAC110-20-790.

18VAC110-20-750. Eligible drugs.

A. Drugs may be accepted by a registered drug donation site only if the following criteria are met:

1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, as set forth in § 54.1-3411.1, subdivision A2;

2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and

3. The drugs have not been adulterated or misbranded.

B. The following drugs shall not be accepted by a drug donation site:

1. Schedule II-V controlled substances or any other drug, if such return is inconsistent with federal law;

2. Drugs determined to be hazardous for donation based on the pharmacist's professional judgment, experience, knowledge, or available reference materials;

3. Drugs that may only be dispensed under a restricted distribution system for safety reasons to include drugs that may only be dispensed to a patient registered with the drug manufacturer; and

4. Drugs that have been previously compounded.

18VAC110-20-760. Procedures for collecting eligible donated drugs.

A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long term care facility or other facility where drugs are administered to that patient, if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

1. A statement that the donor is the patient or patient's agent for whom the prescription drug was dispensed;

2. A statement that the donor intends to voluntarily donate the prescription drug for re-dispensing;

3. A statement attesting that the drugs have been properly stored at all times while in the possession of the patient according to official compendium storage requirements;

4. Contact information of the patient or patient's agent;

5. The date of donation;

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6. A listing of the donated drugs to include name, strength, and quantity;

7. A statement that private health information will be protected;

8. The signature of the patient or patient's agent; and

9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.

D. Donated prescription drugs shall be stored within the prescription department, separate from other drug inventory.

E. Prior to transferring any donated drugs or re-dispensing donated drugs, a pharmacist shall perform a final review of any donated drug for eligibility and shall ensure that all the donor's patient specific information has been removed from previous labeling or rendered unreadable.

F. A drug donation site may not charge a fee for collecting donated drugs.

18VAC110-20-770. Procedure for transferring donated prescription drugs.

A. A drug donation site may transfer eligible donated prescription drugs to another drug donation site for the purpose of re-dispensing.

B. The transferring drug donation site shall provide a transfer record to the receiving drug donation site that includes the following:

1. The names and addresses of the transferring site and the receiving site;

2. The name, strength, and quantity of each donated drug being transferred; and

3. The date of transfer.

B. The original transfer record shall be maintained by the transferring drug donation site.

C. A copy of the transfer record shall be provided to the receiving drug donation site, the date of receipt shall be recorded on the copy, and it shall be maintained by the receiving drug donation site.

18VAC110-20-780. Procedure for dispensing donated prescription drugs.

A. A drug donation site re-dispensing donated prescription drugs shall comply with applicable federal and state laws and regulations for dispensing prescription drugs.

B. The pharmacy re-dispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing fee for each such drug re-dispensed, not to exceed the current Medicaid dispensing fee.

C. Recipients of a re-dispensed donated drug shall sign a form prior to receiving the drug that includes a statement that the recipient understands that the drug received has been donated for

the purpose of re-dispensing pursuant to §54.1-3411.1. The drug donation site shall maintain this form.

D. A drug donation site is under no obligation to obtain a prescription drug that is not in inventory at the time of a request for such drug.

18VAC110-20-790. Procedures for disposing of donated prescription drugs.

A. A drug donation site in possession of donated prescription drugs ineligible for re-dispensing shall dispose of such drugs in compliance with 18 VAC110-20-210.

B. A drug donation site shall maintain records of disposal or transfer for disposal of donated prescription drugs separately from other pharmacy disposal records.

18VAC110-20-800. Records

A. All records required for drug donation programs shall be maintained chronologically for two years.

B. Records and prescriptions related to donated drugs shall be maintained separately from other pharmacy records.

C. Storage of records.

1. Transfer, dispensing, and disposal records may be stored in an electronic database or record or as a scanned image;

2. Prescriptions and signed forms, as well as any other records, may be stored as an electronic image which provides an exact, clearly legible, image of the document; or

3. Records may be stored in secured storage, either on or offsite.

D. All records in offsite storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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INTRODUCED

084424592

HOUSE BILL NO. 86

Offered January 9, 2008

Prefiled December 13, 2007

A BILL to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 8, consisting of sections numbered 54.1-3472.1 through 54.1-3472.2, relating to disposal of unused pharmaceuticals.

Patron—Landes

Committee Referral Pending

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 8, consisting of sections numbered 54.1-3472.1 through 54.1-3472.2, as follows:

Article 8.

Unused Pharmaceutical Disposal Program.

§ 54.1-3472.1. Program created.

The Unused Pharmaceuticals Disposal Program is established to ensure the safe, effective, and proper disposal of unused pharmaceuticals. For the purpose of compliance with federal law and regulations, the return of any pharmaceuticals pursuant to this article is deemed to be for law-enforcement purposes.

The program shall be administered by the Virginia Department of State Police ("Department") in cooperation with the Board of Pharmacy ("Board").

§ 54.1-3472.2. Return of pharmaceuticals; disposal.

The Department, together with the Board, shall establish a system for the return of unused pharmaceuticals to a single collection location, which shall be under the control of the Department. The Department shall ensure that only Department officers handle unused pharmaceuticals collected pursuant to this article.

Unused pharmaceuticals shall be disposed of by the Department in a manner determined by the Board to be in compliance with local, state, and federal law and regulation, including environmental regulations.

INTRODUCED

Oregon Pharmaceutical Take Back Stakeholder Group

Executive Summary

Complete report available at www.oracwa.org

In Clackamas County, a 40-year old mother of two died from an accidental overdose of Methadone. She was having difficulty sleeping and decided to try a family member's unused prescription drug left in her medicine cabinet.

Teenagers age 12 to 17 are the fastest-growing group of prescription drug abusers. They arrange "pharming parties" where they swap drugs found in their homes.

Drugs are being found in waterways nationwide; some of them reach the environment by being flushed down the toilet. One study showed male chinook salmon to be very susceptible to sex reversal.

Unused drugs kept in medicine cabinets, tossed in the garbage, or flushed down the toilet or drain can be serious threats to human and environmental health. Drugs of concern include controlled and non-controlled prescription drugs, as well as over-the-counter medications. Drug take back programs -- government or industry programs where unused drugs are returned to designated sources -- reduce avoidable poisoning of both children and adults; prevent intentional misuse of unwanted prescription drugs, especially by teenagers; and protect water quality, fish and other aquatic species.

Why Oregon Needs a Drug Take Back Program

Based on industry estimates, 3% of the prescriptions written in the US are unused. In Oregon, that translates to a possible 1,004,200 prescriptions unused annually in Oregon - 663,000 from residents and another 341,000 from long-term care facilities. Some of these unwanted and unused prescription drugs reach Oregon's environment. How do they get there? The majority is from people taking medicine and excreting it. However, studies show that because of inadequate disposal options, most people throw unused or unwanted drugs away -- either flushing them down the toilet, or disposing of them in the household trash. Adult care facilities in Oregon serve about 35,000 people, and they typically flush unwanted or leftover medications down the drain.

Reduce Avoidable Poisonings

Leftover drugs can result in the unintentional use of wrong or expired prescriptions by people of all ages, poisoning of children who get access to drugs, and poisoning of children and pets who find discarded medication in the trash. In 2004, the Oregon Poison Center received 28,734 calls for accidental poisonings of children under six years old, which represented 77% of the pediatric hospital visits in Oregon that year. Overall, drugs represent the most common poisoning hazard, resulting in 50% of all avoidable poisoning calls.

Prevent Intentional Misuse of Drugs, Especially by Teenagers

Misuse of unwanted prescription drugs is the nation's second prevalent drug problem, after marijuana use. From 2002 to 2004, Oregon had the third highest rate in the nation (10%) among youths for non-medical use of pain relievers. Oregon also ranks in the top five states with the highest prevalence of stimulant misuse for ages 12 years and older. Estimates show that the state of Oregon may have nearly 15,000 Emergency Room visits per year from the nonmedical use of drugs. These are often severe. In a national study, 33% of such emergencies resulted in the patient being sent to a critical care unit. Misuse can also result in dependence or abuse of a drug, and those at greatest risk are between the ages of 12 and 25. The Pacific Northwest ranks third in the nation for drug dependence and abuse.

Protect Water Quality

In one national study of 139 streams in 30 states, drugs were found in 80% of the samples. The two biggest concerns of aquatic impacts are hormone disruption in fish and effects of antibiotics. In the Potomac River, male fish were discovered producing eggs. In Colorado, native fish populations in Boulder Creek showed significant endocrine disruption.

Drugs from households and care facilities reach waterways from excretion, flushing drugs down the toilet into sewers and septic systems, and trash disposal resulting in landfill leachate that reachs surface water or infiltrates groundwater. Some drugs can be treated at traditional wastewater treatment plants, but others cannot. While the

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majority of drugs enter the water through human excretion, a drug take back program is still an important step in reducing chemicals in the environment.

The Work of the Drug Take Back Stakeholder Group

A select group of Stakeholders, along with interested parties, formed the working group in October, 2006 to study the disposal of unwanted and unused drugs in Oregon. Stakeholders included a breadth of expertise ranging from law and drug enforcement; public water agencies; pharmaceutical groups; environmental organizations; medical, health care, recycling and poison center representatives; and city and county governments. The group focused on unwanted drug disposal from households and care facilities.

The Stakeholders researched and analyzed existing and proposed drug take back programs in other places including British Columbia, the states of Maine and Iowa, and efforts in other U.S. counties and areas. Methods of drug return range from prepaid mail-in envelopes to drop boxes at pharmacies or law enforcement agencies; the benefits and drawbacks of each were explored.

The Stakeholders' task was to create a proposed program for Oregon that is effective, fair, and economical, and includes both controlled and routine drugs. The program should also include education and outreach elements, needs to work in both urban and rural areas of the state, and must have a long-term funding base.

Oregon Program and Funding Recommendations

The Stakeholders' recommendation, endorsed by the majority of the group, is based on the successful, British Columbia Medications Return Program that has been in operation since 1996. There, an organization of pharmaceutical manufacturers known as the Post Consumer Stewardship Association organizes and finances the program. This is known as a Product Stewardship program.

Based on the success of the British Columbia program, estimates for Oregon indicate that approximately 60,000 pounds of unwanted drugs would be returned annually, including about 5,300 pounds of controlled drugs such as narcotics, Vicodin, Demerol, Ritalin, or Xanax.

The majority of the group believes that this approach, which has been used by other industries in the U.S. and Canada, has the best potential for success. The Pharmaceutical Research and Manufacturers of America (PhRMA), opposes the recommendations.

Program Proposal: Product Stewardship Program

In a Product Stewardship Program, pharmaceutical manufacturers and over-the-counter drug companies would be requested to devise and implement a convenient and effective program for consumers to dispose of unwanted medicine. The industry can select the format -- mail-back, drop box, a combination of the two, or another concept that the industry may choose to pursue. In addition, the program for Oregon should seek federal Drug Enforcement Administration waivers (as Washington, California and Maine have already requested) to allow controlled drugs to be included.

Action by the 2007 Oregon Legislature included pharmaceutical take back programs as one program to examine to reduce toxics in Oregon's water. If the industry is unable to move forward with such a program, the Stakeholders propose that legislation requiring it be introduced in the 2009 Oregon Legislature.

Funding Proposal: Industry Funding

The Stakeholders do not believe that the burden of this program should fall directly on consumers, nor be added as an additional cost to the routine responsibilities of Oregon's law enforcement agencies. In 2005, the BC program collected 39,710 pounds of unwanted drugs at a total cost of $190,935 (U.S. dollars). The group recommends that the industry fund the program, although the Pharmaceutical Research and Manufacturers of America, does not support this option.

The funding method proposed is similar to that in British Columbia and in the recycling of used batteries, mercury-containing thermostats, and electronic equipment in some states including Oregon. This option keeps the program financing directly related to the producers, users, and disposers of medications, instead of spreading the costs across the general public. A private sector system can be designed to be efficient and flexible.

Drug Take Back -- A Simple, Safe Routine

Take-back programs have become common, simple routines throughout Europe and Canada for a wide range of hazardous products including pharmaceuticals, automotive fluids, batteries, electronics, paint, solvents, tires and other products. They are becoming more commonplace in the U.S. Oregon already has a program in place for battery recycling and the Legislature recently passed an electronics recycling program. Take back programs for drugs are of even greater consequence. A proactive approach will help avoid poisonings and drug addiction, and is more cost-effective than treatment in both public health and pollution control.

A safe and secure program can make the collection and disposal of unused and unwanted drugs as easy and convenient as buying a bottle of aspirin or filling a doctor's prescription, while bringing benefits for the health of Oregonians and the environment.

July, 2007

Complete Report Avaliable at:
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1 Executive Summary

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2 Stakeholder Membership and Group Process

2.1 Project Background

In April of 2006, the federal Drug Enforcement Administration (DEA) organized a two-day conference in Portland, Oregon focused on ***End User Drug Disposal.*** A variety of national and regional experts in drug disposal issues attended and made presentations including:

- Kenneth Magee, DEA Seattle Field Division, Portland District Office;
- John Cavendish, Office of Diversion Control, DEA – Headquarters;
- Dr. Christian Daughton, Environmental Sciences Division, EPA Office of Research and Development;
- Dr. Stevan Gressitt, Maine Benzodiazepine Study Group;
- Jeff McLennan, Clackamas County Medical Officer;
- Gary Schnabel, Oregon Board of Pharmacy; and
- Others.

Regional experts from the state of Washington—including both the Clark County program and the Washington ***Pharmaceuticals from Households: A Return Mechanism*** (PH:ARM) program—attended, along with Department of Environmental Quality staff, municipalities, and others.

At the conclusion of the conference, Oregon participants continued to discuss how an Oregon statewide drug take back program might be structured.State and local governments funded a collaborative effort to gather stakeholders interested in an Oregon pharmaceutical take-back program, and to staff the group to develop a consensus set of recommendations.

The funding agencies for this stakeholder process included:

- Oregon Department of Environmental Quality;
- Oregon Association of Clean Water Agencies;
- Oregon Water Utilities Council;
- Eugene Water and Electric Board;
- City of Eugene – Pollution Prevention Program;
- City of Springfield – Pollution Prevention Program;
- Tualatin Valley Water District;
- Sunrise Water Authority; and
- City of Bend.

2.2 *Stakeholder Membership*

A select group of stakeholders were chosen to participate in the Stakeholder Group with each organization selecting their own representative to participate. Not all the groups identified as stakeholders participated in the group. In addition, interested parties also participated in the Stakeholder meetings. At the conclusion of the first meeting, additional stakeholders were identified and asked to participate. Stakeholders and interested parties are listed in Table 2.2a and Table 2.2b.

Table 2.2a: Drug Take Back Stakeholders

FIRST	LAST	ORGANIZATION
Tony	Burtt	Oregon Board of Pharmacy
Tom	Penpraze	City of Corvallis
Jim	Hill	Oregon Association of Clean Water Agencies (City of Medford)
Brett	Hulstrom	City of Portland Bureau of Environmental Services
Jeff	McLennan	Clackamas County Medical Examiner*
Linda	Fleming	Council of Local Public Health Officials*
Kelly	Champion	Covanta Marion*
Lis	Houchen	National Association of Chain Drug Stores
Kevin	Campbell	Oregon Association Chiefs of Police*
Abby	Boudouris	Oregon Department of Environmental Quality
Teresa	Huntsinger	Oregon Environmental Council
Ann	Jackson	Oregon Hospice Association
Tanya	Drayden	Oregon Poison Center
Lisbeth	Ward-Fowler	Oregon Poison Center (alternate)
Dave	Leland	Oregon Public Health Division – Drinking Water Program
Kristan	Mitchell	Oregon Refuse & Recycling Association
Holly	Sears	Oregon Refuse & Recycling Association (alternate)
Dave	Burright	Oregon Sheriffs' Association*
Gerry	Migaki	Oregon Society of Health-System Pharmacists
Jim	Thompson	Oregon State Pharmacy Association
Rebecca	David	Oregon State Police
Michael	Dingeman	Oregon State Police
Lacey	Bettis	Oregon State Police (alternate)
Leslie	Wood	Pharmaceutical Research and Manufacturers of America (PhRMA)
Jim	Solvedt	Polk County (alternate)
Brenda	Bateman	Tualatin Valley Water District (Oregon Water Utilities Council)
Bill	Etter	U.S. Drug Enforcement Administration

** Did not participate or attend one meeting or more, either by the phone or in person*

Table 2.2b: Drug Take Back Interested Parties

FIRST	LAST	ORGANIZATION
Margo	Barnett	
Darcy	Hitchcock	Axis Performance
Theresa	Briggs	City of Bend
Peter	Ruffier	City of Eugene
Sharon	Olson	City of Eugene
Karen	DeBaker	Clean Water Services
Marney	Jett	Clean Water Services
Paul	Larsen	Consumer Healthcare Products Association
Bruce	Hammon	Department of Environmental Quality
Jennifer	Boudin	Department of Environmental Quality
Pamela	Brody-Heine	Eco Stewardship Strategies
Karl	Morgenstern	Eugene Water & Electric Board
Nancy	Toth	Eugene Water & Electric Board
Jim	Gardner	Gardner & Gardner
Bruce	Lott	Generic Pharmaceutical Association (GPhA)
Jennifer	Seely	Kaiser Permanente NW
Sarah	Chaplen	League of Women Voters
Jill	Leary	Lower Columbia River Estuary Partnership
Jeff	Bickford	Marion County Public Works
Kim	Dinan	Marion County Public Works
Scott	Klag	Metro
David	Stitzhal	Northwest Product Stewardship Council
Shawn	Miller	Oregon Community Pharmacy
Amy	Parmenter	Oregon Department of Human Services
Robert	Bailey	Oregon Department of Human Services
Michael	Stupfel	Oregon State Police
Monica	Hubbard	Oregon State University
Debra	Taevs	Pollution Prevention Resource Center
Lorna	Stickel	Portland Water Bureau
Rebecca	Geisen	Portland Water Bureau
Sego	Jackson	Snohomish County Solid Waste Management Division
John	Thomas	Sunrise Water Authority
Kim	Anderson	Sunrise Water Authority
Elena	Nilsen	U.S. Geological Survey (USGS)
Larry	Chalfan	Zero Waste Alliance

2.3 *Group Process*

Initially the stakeholder group reviewed, modified, and accepted a charter to guide its process at the first meeting. A copy of the adopted charter is included in Appendix A. Stakeholders and interested parties met for the first time on November 9, 2006. Also in November 2006, many in the group participated in a daylong workshop to learn about drug take back programs and regulatory issues.

Additional meetings of the Stakeholder group included:

- February 9, 2007
- March 9, 2007
- April 13, 2007
- May 11, 2007
- June 15, 2007
- July 13, 2007

Meeting summaries located in Appendix B.

Three sub-groups were formed out of the larger stakeholder group to develop detailed recommendations for the major sources of unwanted drugs including, Adult Care Facilities (also known as Long Term Care Facilities), hospitals, and the general public. In addition, Oregon Hospice provided input recommendations for Oregon hospice facilities. The Adult Care Facilities and Hospital groups' findings are detailed in section 7. The general public recommendations were never finalized.

3 Background on Drug Take Back Programs

While many countries and provinces, including Australia and British Columbia, Canada, have a pharmaceutical take back or return system, neither the United States federal government nor the State of Oregon are served by a program. Unused drugs are typically stored and stockpiled in residents' medicine chests in the home, where children or adults can accidentally ingest them. Additionally, due to their accessibility they can lead to prescription drug misuse, abuse and addiction. With the legal restrictions associated with controlled drugs, like OcyContin®, pharmacies are not legally able to take back many unneeded drugs.

Controlled drugs are drugs, or other substances, included in Schedule I, II, III, IV, or V of Title 21, Code of Federal Regulations (CFR), Sections 1308.11 to 1308.15 (National Archives and Records Administration 2004; Office of Diversion Control 2006). Any substance not on the schedules are noncontrolled (Bateman, Thonstad, and Danicic 2007).

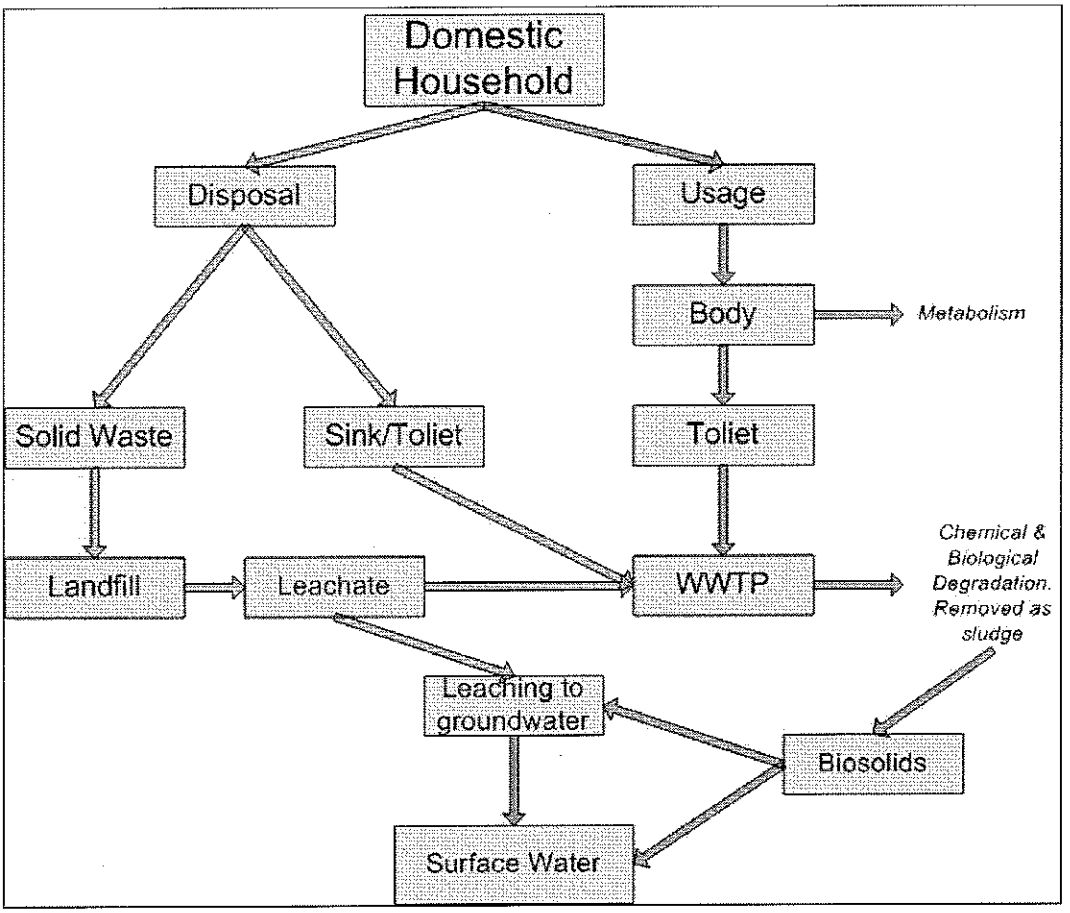
There are numerous sources of unwanted pharmaceutical drugs that can lead to water contamination: residential homes, adult or long term care facilities, health care facilities such as clinics and hospitals, veterinarian clinics, and agricultural operations. As displayed in figure 3, the two main paths pharmaceutical drugs enter the aquatic environment from households are excretion after use or disposal before ingestion via the trash and or the sewer and septic systems, usually after being flushed down the toilet (Daughton and Ternes 1999; U.S. Environmental Protection Agency 2006; Kostich and Lazorchak 2006).

A 1993 investigation into the disposal habits of the public found that only 1.4% of people surveyed returned unused medication to the pharmacy, whereas 54% threw them away and 35.4% disposed of them in the sink/toilet (Kuspis and Krenzelok 1996). A survey conducted as part of the San Francisco Bay Area's Safe Medicine Disposal Days in May 2006 found that of the more than 1,500 residents that participated, more than 25% had previously disposed of medication down the sanitary sewer, while close to half previously disposed of medication in the trash (Bay Area Pollution Prevention Group, 2006). While it is unknown how many of the pharmaceutical compounds found in the aquatic environment are from improper disposal before use or excretion after use, it is presumed the majority is from excretion after use.

At a May 22, 2007 convention in California, the pharmaceutical industry presented that, according to their best estimate, about 3% of prescribed drugs are unused and disposed of via the trash or sewer (Buzby 2007). Of that, they estimate about 66% is attributed to individual use, while the remaining 34% of unused drugs are from long term care facilities (Buzby 2007). Since Oregon accounts for about 1% of the United States prescribed drugs[1] with 33,473,641 prescriptions in 2005 (Henry F. Kaiser Family Foundation 2007), using the pharmaceutical industry's estimated rate of disposal of 3%, potentially 1,004,209 unused pharmaceutical prescriptions are disposed in Oregon. Furthermore, using the pharmaceutical industry's estimates, about 662,778 unused pharmaceutical prescriptions potentially released into Oregon's environment could come from residents and 341,431 from long tern care facilities.

[1] In 2005 there were an estimated 3,192,641,028 prescriptions in the Untied States, of which Oregon accounted for 33,473,641, which equates to 1%.

Figure 3: Pharmaceutical pathway into surface water.[2] (Adapted from Bound and Voulvoulis 2005).



3.1 *Problem Statement*

Many Oregon households, adult care facilities, and health care facilities possess unused and outdated prescription and over-the-counter drugs. Often these medications are stockpiled in a cabinet, creating potential safety and environmental problems; issues that will only increase with the ageing population and increase in pharmaceutical drug use. From 2005 to 2006, the number of pharmaceutical prescriptions increased by 4.3% in the United States (National Association of Chain Drug Stores 2007).

The three key reasons Oregon should develop a successful pharmaceutical take-back program are to:

1. Reduce avoidable poisonings;
2. Prevent prescription drug misuse and abuse; and
3. Protect water quality, which subsequently protects drinking water and the health of aquatic species.

[2] WWTP: wastewater treatment plant.

The main goal of the pharmaceutical drug return program is to provide a disposal method to reduce unwanted pharmaceutical drug availability, and thus reduce accidental poisonings and intentional drug abuse. Since it's impossible to quantify the extent a program will reduce the pharmaceutical compounds in water, the protection of water quality is both precautionary step, and to raise the general public's awareness of the water quality issues.

3.1.1 REDUCE AVOIDABLE POISONING

Unused or unwanted drugs can lead to serious health and safety problems, including:

- Unintentional use of wrong prescriptions;
- Unintentional poisoning of children in the home; and
- Unintentional poisoning of children and pets that find discarded medication in the trash.

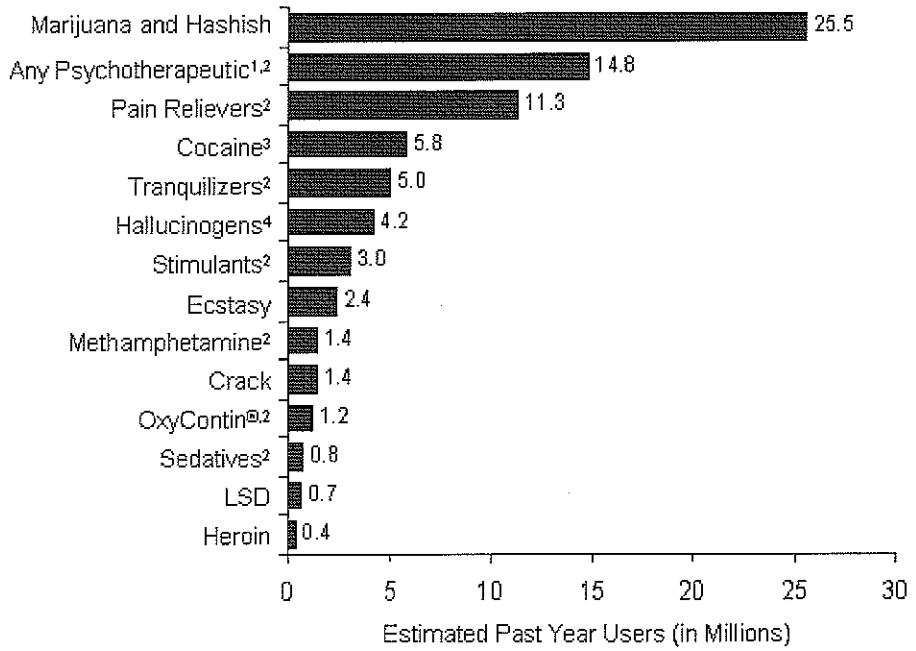
In 2004 the Oregon Poison Center (OPC), the designated regional poison center for Oregon, Alaska, Northern Nevada and Guam, received 71,677 calls for assistance; 76% of the calls were regarding human exposure to poison and the rest for information or animal exposures.[3] Pediatric (under 6 years of age) accidental poisoning represented 52% of the calls, with 28,734 cases. Pharmaceutical drugs were the most common category of exposure, resulting in 50% of the accidental poisoning calls, and represented the most serious poisoning incidents. Poisoning from pharmaceutical drugs were 85% of the 11,393 calls that required hospital visits in 2004. Poisoning with pharmaceutical drugs resulted 77% of the pediatric hospital visits in Oregon in 2004 (Oregon Poison Center 2004). Within the United States, unintentional poisoning deaths are the second leading cause of injury death for 35-54 year olds and the third leading cause of injury death for 25-34 year olds (Health Resources and Services Administration 2007).

3.1.2 PREVENT INTENTIONAL MISUSE, DEPENDENCE AND ADDICTION OF PRESCRIPTION DRUGS

Intentional *'**nonmedical**'* abuse of pharmaceutical drugs by youths, categorized as ages 12 to 17, has become an increasingly disturbing issue. ***Nonmedical*** use is defined by the National Surveys on Drug Use and Health (US Substance Abuse and Mental Health Service Administration 2005) Department of as use of these medications without a prescription of the respondent's own or simply for the experience or feeling the drug caused. Thus, nonmedical use does not include legitimate use of prescription drugs under a physician's direction, nor does it include use of over-the-counter medications. While misuse of prescription drugs is second only to marijuana as the nation's most prevalent drug problem (see figure 3.1.2.a), the annual average number of people using pain relievers nonmedically for the first time exceeds the number of new marijuana users (Colliver *et al.* 2006) . During the years 2002-2004 Oregon had the third highest rate (10%) among youths for nonmedical use of pain relievers; the highest rates were in Washington (10.7%) and Kentucky (10.2%). Oregon also ranks in the top five states with the highest prevalence of stimulant misuse for ages 12 years and up (Colliver *et al.* 2006).

[3] Statistics are for the Oregon Poison Center region, and include Guam, Oregon, Alaska, and Northern Nevada,

Figure 3.1.2.a: Past Year Users of Selected Drugs, Including Nonmedical Users of Prescription Psychotherapeutic Drugs: Annual Averages Based on 2002-2004 (Colliver *et al.* 2006)[4]



The increase in nonmedical misuse of prescription drugs can potentially be attributed to the sharp increase in commercial disbursements of controlled pharmaceuticals (prescription narcotics, depressants, and stimulants) around the nation, which has led to an overall increase of drugs available of illicit use. According to National Drug Intelligence Center's National Drug Threat Assessment of 2006, from 2000 through 2004 commercial disbursements of pharmaceuticals increased 109%, yet during that same period commercial disbursements of commonly abused pharmaceuticals, such as oxycodone and hydrocodone, increased at an even greater rate of 209%, see figure 3.1.2.b. While the assessment also found that overall illegal diversion is primarily conducted through theft, forged prescriptions, doctor shopping, and via the Internet; most young people aged 12 to 17 get these drugs from friends or family members for free, not the Internet (Substance Abuse and Mental Health Services Administration 2006).

[4] Explanation of chart footnotes:

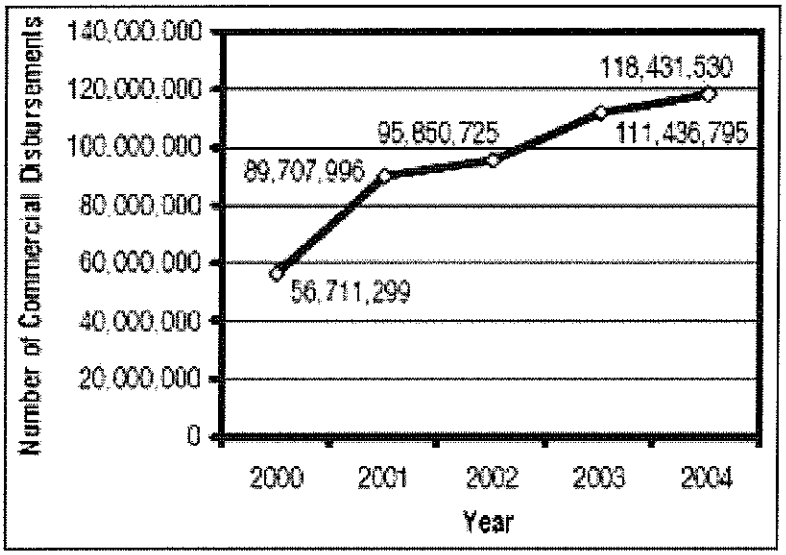
[1] Includes pain relievers, tranquilizers, stimulants, and sedatives.

[2] Nonmedical use only. OxyContin® also is included with pain relievers, and methamphetamine also is included with stimulants. The OxyContin® estimate is based on 2004 data only.

[3] Includes crack.

[4] Includes lysergic acid diethylamide (LSD), phencyclidine (PCP), and Ecstasy.

Figure 3.1.2.b: Commercial disbursements of commonly abused pharmaceuticals, United States, 2000-2004 (Colliver *et al.* 2006)[5].



3.1.2.1MEDICAL TREATMENT

Nonmedical use of prescription drugs can result in unintended, costly medical emergencies. The Drug Abuse Warning Network (DAWN) is a public health system that monitors drug related visits to hospital emergency rooms and drug related deaths in the United States. DAWN defines "medical use" as taking a prescription or over-the-counter pharmaceutical as prescribed or recommended, and "nonmedical use" as use that does not meet the definition of medical use. Thus, nonmedical use of pharmaceuticals includes taking more than the prescribed dose of a prescription pharmaceutical or more than the recommended dose of an over-the-counter pharmaceutical or supplement; taking a pharmaceutical prescribed for another individual; deliberate poisoning with a pharmaceutical by another person; and documented misuse or abuse of a prescription or over-the-counter pharmaceutical or dietary supplement. Nonmedical use of pharmaceuticals may involve pharmaceuticals alone or pharmaceuticals in combination with illicit drugs or alcohol. It's important to note that DAWN cannot distinguish between those cases of illicit use from the cases where a patient is provided drugs and accidentally overdoses.

According to the DAWN 2005 annual report, there were an estimated 598,542 emergency department visits in the United States for nonmedical use of pharmaceuticals, and could be as many as 710,314[6]; a 21% increase from 2004 (Ball, Johnson, and Foley 2005). Of those, 20% involved a combination of drugs with alcohol, 20% involved a combination of pharmaceuticals and illicit drugs, and 6% involved pharmaceuticals, illicit drugs and alcohol. DAWN estimates about 404 visits per a population of 100,000. Thus, the state of Oregon, with an estimated

[5] Commonly abused pharmaceuticals include codeine, methylphenidate, oxycodone, hydromorphone, hydrocodone, meperidine, methadone, morphine, fentanyl, cocaine, d-methamphetamine, d-amphetamine, and dl-amphetamine.

[6] DAWN cases are identified through a retrospective review of medical charts. Given the limitations of medical record documentation, DAWN concluded that distinguishing misuse from abuse reliably is not feasible.

population of 3,690,505 in 2006 (Population Research Center 2006), could have an estimated 14,910 emergency department visits per year for nonmedical use of pharmaceuticals. It should be noted that this is an estimate, and data is currently not available to know the exact number of emergency room visits for Oregon, and whether or not they were for illicit pharmaceutical use, or prescribed medication.

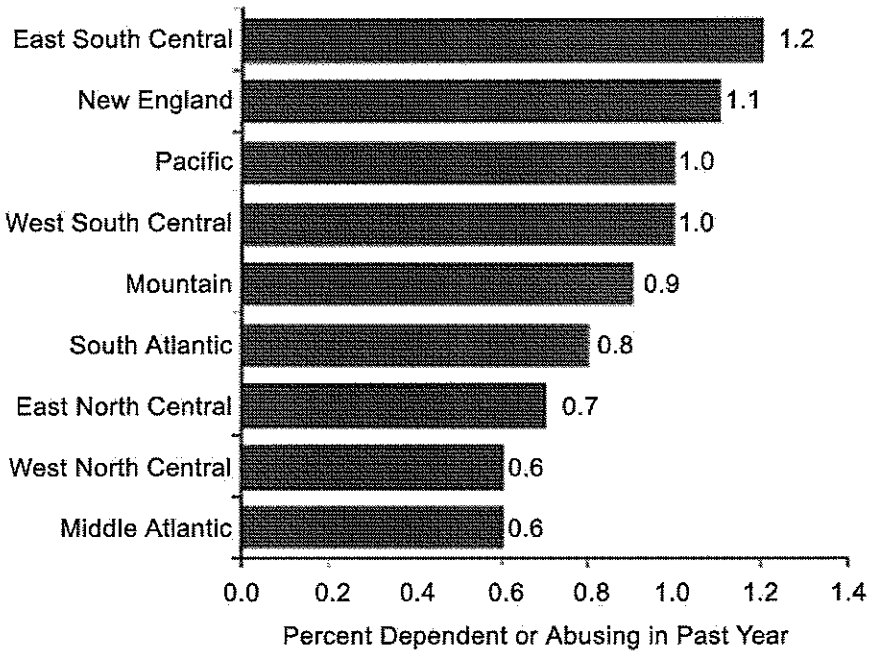
Using national estimates, in 55% of the visits, patients were treated and released, with 88% of those discharged home and 8% referred to a detoxification clinic or substance abuse treatment. In 33% of all nonmedical use visits, patients were admitted to inpatient hospital units. Of those admitted to the hospital, 33% were sent to a critical care unit, about 15% to a psychiatric unit, and 48% to other inpatient units. About 7% of emergency department visits for nonmedical use of pharmaceuticals resulted in transfers to another health care facility (Ball, Johnson, and Foley 2005).

Lack of documentation inside medical records makes it impossible to determine whether or not the abused drug was prescribed or obtained illegally. Additionally, it is not possible to ascertain whether or not some of individuals included in the data are actually abusing prescription drugs, or patients that may have purposely taken more than the prescribed amount of medication for treatment.

3.1.2.2 PRESCRIPTION DRUG DEPENDENCE AND ABUSE

Misuse can pass a threshold and result in dependence or abuse of a prescription drug. Within the ***Diagnostic and Statistical Manual of Mental Disorders***, 4th edition (DSM-IV) (Colliver *et al.* 2006), the questions to determine drug dependence ask about continued use despite health or emotional problems associated with substance use, unsuccessful attempts to cut down on use, tolerance, withdrawal symptoms, reducing other activities in order to use substances, spending time engaging in activities related to substance use, or using the substance in greater quantities or for a longer time than intended. The questions regarding abuse focus on problems at work, home, and school; problems with family or friends; physical danger; and trouble with the law due to substance use. Those at greater risk of abusing or becoming dependent are between the ages of 12 to 25. In the United States, an estimated 2 million people are either dependent or abusing prescription drugs. The Pacific Region of the United States, where Oregon is located, ranks third in the nation for drug dependence and abuse; see figure 3.1.2.2. Other states included in the Pacific Region include Alaska, California, Hawaii, and Washington.

Figure 3.1.2.2: Substance Dependence or Abuse for Nonmedical Use of Any Prescription Psychotherapeutic Drug in the Past Year, by Census Division: Annual Averages Based on 2002-2004 (Colliver *et al.* 2006).



Nationwide in 2002, 2003, and 2004, an annual average of 290,000 persons received treatment for illicit drug use in the past year and met the criteria for dependence on or abuse of prescription psychotherapeutic drugs in the past year (Colliver *et al.* 2006).

3.1.3 PROTECT WATER QUALITY

The two main paths pharmaceutical drugs enter the water system from homes and health care facilities are excretion after use or direct disposal via the trash and/or flushing into the sewer or septic system (U.S. Environmental Protection Agency 2006; Daughton and Ternes 1999; Kostich and Lazorchak 2006). Internationally, evidence of pharmaceutical drugs has shown up in numerous water sources. Within the United States, a United States Geological Survey (USGS) study found pharmaceuticals, hormones, and other organic wastewater contaminants in 80% of the 139 streams sampled in 30 states (Kolpin *et al.* 2002; Cocke 2004). USGS reconnaissance data found detectible levels of pharmaceuticals and other microcontaminates in Oregon streams, including samples from the Tualatin River, Zollner Creek near Mt. Angel and the Willamette River near Swan Island.

Conventional wastewater treatment plants are designed to remove traditional pollutants including solids, biochemical oxygen demand, bacteria, and viruses. Some treatment plants are also designed to remove nutrients, such as phosphorus. National research is underway to determine the extent that these traditional treatment technologies can remove microcontaminants; preliminary results indicate that some microcontaminants, such as pharmaceuticals and personal care products, can be treated at a traditional treatment plant, but others cannot.

In Oregon, 62 wastewater treatment plants and 52 industrial and commercial dischargers are upstream of public drinking water sources. Combined, these public drinking water sources serve 651,000 Oregonians.

3.1.3.1 Solid Waste Leachate

Dr. Jeff Nason, Oregon State University, conducted a review of available literature regarding the absence or presence of pharmaceuticals in landfill leachate or groundwater below unlined landfills as part of this report. A copy of the complete report is included as Appendix B. The report conclusions included:

> *A wide variety of pharmaceutical compounds have been detected in landfill leachate from lined landfills and in groundwater down gradient of unlined landfills. The presence or absence of pharmaceuticals does not appear to be correlated with the operating status of the landfill (active vs. closed). However, a larger number of closed landfills were unlined and therefore posed a greater risk of direct contamination of the groundwater. Neglecting the sites thought to be contaminated with hospital (Eckel et al., 1993) or pharmaceutical production waste (Holm et al., 1995; Abel et al., 1998; Abel and Jelicic, 2001), concentrations of pharmaceutical compounds in leachate ranged from less than 10 ng/L to as high as 120 ig/L. In contaminated groundwater, concentrations ranged from < 1 ng/L to as high as 140 ig/L. Much higher concentrations (up to 18 mg/L) were found in groundwater contaminated by unlined landfills that had received pharmaceutical production waste.*
>
> *The potential benefits of disposing pharmaceutical compounds to landfills are the partitioning of some pharmaceuticals to organic matter and biological or chemical degradation within the landfill. However, the fraction of the pharmaceutical compounds that end up in the leachate must be removed prior to surface water discharge; some fractions of those compounds can escape treatment and end up in the environment. Theoretical predictions (Tischler/Kocurek, 2007) and field data (Schneider et al., 2004) suggest that drugs disposed of in municipal solid waste landfills contribute only a small fraction (< 1%) of the total load of pharmaceutical compounds discharged to surface water via municipal wastewater treatment plants and landfill leachate treatment systems. However, for individual compounds, this percentage is estimated to be as high as 20%. Although the total load of pharmaceuticals to surface waters is predicted to be small, it is not zero. Furthermore, the likelihood that drugs disposed of in landfills will ultimately end up in surface water is compound specific. These preliminary studies provide a starting point, but further research is necessary to more completely understand the transformation and ultimate fate of pharmaceutical compounds in landfill leachate. To date, only a few studies have examined the concentrations of pharmaceutical compounds in leachate from lined landfills (Paxeus, 2000; Schneider et al., 2001; Schwarzbauer et al., 2002; Breidenich, 2003; Heim et al., 2004; Schneider et al., 2004) and all of those studies focused on landfills in countries other than the U.S. Additional study in the U.S. is necessary to more fully evaluate the occurrence and fate of pharmaceuticals in landfill leachates and the potential implications of the White House Office of National Drug Control Policy's guidance directing consumers to dispose of unused pharmaceuticals in household trash.*

As displayed in figure 3.1, pharmaceuticals disposed in solid waste landfills escape in the form of leachate, the liquid that has passed through or emerged from landfill waste. Leachate contains soluble, suspended, or miscible materials removed from the waste. While newer landfills are designed with a leachate collection system, typically the collected leachate is transported to a wastewater treatment plant for treatment. In older landfills without a collection system, the leachate can infiltrate the groundwater or move to surface water. In 2000 the USGS conducted a study of the Norman Landfill located in Oklahoma. The landfill, which was opened in 1920 and closed in 1985, did not have a leachate collection system. According to the study, the leachate plume is moving in the direction of ground water flow and has migrated beyond a wetland that is about 394 feet south of the landfill. The samples collected found 22 organic wastewater contaminants, including pharmaceuticals (Barnes *et al.* 2004).

3.1.3.2 Impacts from On-Site Wastewater Treatment Systems

Oregon residents outside cities and towns often use on-site or septic systems for wastewater treatment and disposal, which reintroduce treated effluent into the soil below the surface. Unwanted drugs disposed of in on-site systems can damage an on-site wastewater treatment systems, which are dependent on a healthy bacteria community to treat the wastewater.

In the rural-residential community of La Pine, in Oregon's upper Deschutes Basin, the USGS, Oregon DEQ and Deschutes County Environmental Health Division tested the groundwater for organic wastewater compounds, including a suite of 18 pharmaceuticals. The La Pine community relies on individual on-site wastewater systems for wastewater treatment and disposal.Of the 18 pharmaceuticals analyzed for in the onsite wastewater, 8 were detected at concentrations above laboratory reporting levels (Hinkle *et al.* 2005). The groundwater aquifer below La Pine is the sole source of drinking water for La Pine residents.

3.1.4 PROTECT AQUATIC SPECIES

Aquatic species concerns regarding microcontaminants in water quality synthetic estrogens, endocrine disruptor compounds (EDCs), and antibiotics. An example of an EDC is Clofibrate, a drug commonly used to lower cholesterol. On the Potomac River downstream from a wastewater treatment plant, the USGS discovered male fish producing eggs from estrogenic exposure in birth control pills (Cocke 2004; Raloff 2004). One sample found that 79% of the male fish sampled had sexual abnormalities, such as producing egg sac proteins and intersex changes

A 2000 USGS study was conducted on the streams in the Boulder Creek Watershed in Colorado to evaluate the spatial chemical loading on the watershed level. The study was timed to coincide with spring-runoff (June 12-14, 2000) and base-flow (October 9-11, 2000) conditions (Barber *et al.* 2006). Pharmaceutical compounds were detected (55% of the 22 compounds analyzed) in the main stem Boulder Creek samples, including diltiazem, cotinine, and sulfamethoxazole (Barber *et al.* 2006). Although most pharmaceuticals only occurred downstream from the Boulder wastewater treatment plant (WWTP), several (ranitidine, codeine, diltiazem) were detected during spring runoff at the most upstream site. Studies on native fish populations in Boulder Creek indicate significant endocrine disruption in the wastewater treatment plant effluent impacted stream reach. Upstream from the WWTP outfall, the gender ratio (male/female) for white sucker ranged from 0.7-0.9, whereas below the outfall the ratio ranged from 0.2-0.3. Other indicators of endocrine disruption, including gonadal intersex and vitellogenin induction in juvenile and male fish, also were observed (Barber *et al.* 2006).

With salmonids the window when where they are sensitive to estrogen and EDCs is around the time of hatching and extends to beyond the time when these fish begin to feed exogenously; during this window male Chinook salmon have been shown to be very susceptible to sex reversal (Nagler *et al.* 2001).

In March 2007 the U.S. Fish and Wildlife Service and the American Pharmacists Association (APhA) announced their partnership, "to help protect our nation's fish and aquatic resources from improper disposal of medication" (U.S. Fish & Wildlife Service and American Pharmacists Association 2007). The program, titled "SMARxT DISPOSAL", will work to educate the general public on the negative impacts improper disposal into the waterways has on the environment, aquatic resources, and public safety. The pilot began in March 2007 and will expand in 2008.

The Pharmaceutical Research and Manufacturers of America are currently involved in research projects to assess the impacts of pharmaceuticals on aquatic species.

3.1.5 PROTECT HUMAN HEALTH

There is currently little evidence that pharmaceuticals are present in the environment in sufficient quantity to cause significant physical harm. A Danish study looked at the human health from environmental exposure to three common pharmaceuticals, the synthetic estrogen (17á-ethinylestradiol), the antibiotic phenoxymethylpenicillin, and the antineoplastic drug cyclophosphamide. The results indicated a negligible human risk connected to the environmental exposure for the three substances (Christensen 1998).

3.1.6 ECONOMIC COSTS

3.1.6.1 Medical Treatment

Due to patient confidentiality, the economic costs for medical treatment due to accidental poisoning or medical misuse are challenging to quantify. With 576,000 Oregonians lacking health care insurance (Oregon Progress Board 2007), the costs to the state of Oregon could be substantial.

3.1.6.2 Oregon Salmon Recovery Costs

Oregon aquatic life is susceptible to the impacts of endocrine disrupting compounds and synthetic estrogen. Within Oregon significant amount of funding goes towards the recovery costs of endangered salmon runs. In 2006 the federal government spent over $559 million on salmon recovery in the Columbia Basin, with the projected funding for 2007 is $578.1 million, with about half from Congressional appropriations and the remaining from Bonneville Power Administration (BPA) funding.

3.1.6.3 Wastewater Treatment Costs

The most likely additional treatment technology to remove pharmaceuticals from treated wastewater effluent would include microfiltration, installation of membrane filtration, and reverse osmosis. Engineering estimates calculate the installation costs of these systems at between $6 million to $15 million per million gallons of treated effluent. These are installed cost estimates and do not include operations and maintenance, brine disposal, or the energy costs associated with operating the facilities. It is not known if microfiltration and reverse osmosis will remove all pharmaceuticals in wastewater effluent.

For illustration, Table 3.1.6.3 estimates the winter (wet weather) flow of selected treatment plants in the Willamette Valley.

Table 3.1.6.3: Estimated Winter Flow of Selected Plants in the Willamette Valley, Oregon

COMMUNITY	ANTICIPATED WET WEATHER FLOWS	**COST RANGE FOR MICROFILTRATION AND REVERSE OSMOSIS**
Corvallis	75 MGD[7]	$450 million to $1.125 billion
Metropolitan Wastewater Management Commission (Eugene/Springfield)	237 MGD	$1.422 billion to $3.555 billion
Clean Water Services (Urbanized Washington County)	335 MGD	$2.010 billion to $5.025 billion
Portland	450 MGD	$2.7 billion to $6.75 billion

[7] MGD: Million Gallons per Day.

4 Regulatory Framework

4.1 Controlled Substances Act

Under the Controlled Substances Act (CSA), Title 21 of the United States Code, prescription medication falls under two categories, controlled and noncontrolled. Due to their abuse potential, controlled medications are regulated by the U.S. Drug Enforcement Administration (DEA), which enforces the Controlled Substances Act. These substances are drugs, or other substances, included in Schedule I, II, III, IV, or V of Title 21 (National Archives and Records Administration 2004). The Code of Federal Regulations (CFR) Sections 1308.11 to 1308.15 break the schedules down based on their abuse potential, utility of medical treatment, and safety when used under medical supervision (Colliver *et al.* 2006):

- Schedule I, the most restrictive level, includes drugs or other substances with a high potential for abuse, no currently accepted medical use in the United States, and a low level of safety. Drugs and other substances in Schedule I are not approved for use, distribution, manufacture, or importation. Examples include heroin, marijuana, phencyclidine (PCP), and lysergic acid diethylamide (LSD).
- Schedule II drugs have high abuse potential but have currently accepted medical use in treatment, though with severe restrictions. Examples include cocaine, methamphetamine, amphetamines (e.g., dextroamphetamine, Adderall®), morphine, oxycodone (e.g., OxyContin®), and methylphenidate (e.g., Ritalin®).
- Schedule III drugs have abuse potential less than that of Schedule I or II drugs and have currently accepted medical uses in treatment. Some drugs in this category include hydrocodone (e.g., Vicodin®) and butalbital (e.g., Fiorinal®).
- Schedule IV drugs have lower abuse potential than those in Schedule III and currently have accepted medical uses in treatment. These include alprazolam (Xanax®), diazepam (Valium®), and propoxyphene (e.g., Darvon®).
- Schedule V drugs have low abuse potential and recognized medical uses. Examples include cough medicines with codeine (e.g., Robitussin AC®).

Any drugs not listed on schedules I-V are considered noncontrolled and fall out of the jurisdiction of the Controlled Substances Act and law enforcement.

The goal of the Controlled Substances Act is to ensure a closed distribution system - - a controlled substance is under the legal control of a person registered, or specifically exempted by the DEA - - until it reaches the ultimate user or is destroyed. If, for example, a pharmaceutical take back event were to take place, the regulations require law enforcement officers to take possession of any controlled substances collected and to maintain possession of them at all times, including witnessing their destruction. Therefore, once a prescription is filled, only the person to whom it was prescribed or law enforcement personnel can legally be in possession of the drug. Noncontrolled substances are those not listed in Title 21. Additional information available at www.deadiversion.usdoj.gov or http://www.dea.gov/pubs/csa.html.

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4.2 *Health Insurance Portability and Accountability Act*

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 does not apply to unwanted medications (U.S. Department of Health and Human Services 2006). While a pharmaceutical take back program would not have to comply with HIPAA, participants may not feel comfortable returning their prescriptions if they feel their privacy may somehow be exposed by returning medications with their names on the labels; yet sorting of drugs for disposal may require the medication information found on label next to the users name. It should also be noted that it is a federal offence, and under Oregon Revised Statute (ORS) 167.212, a state offence to remove or deface a label of a controlled substance.

4.3 *Oregon Board of Pharmacy*

The Oregon State Board of Pharmacy (OSBP) regulates the practice of pharmacy and enforces laws pertaining to drug outlets, pharmacists and the sale of drugs within the state of Oregon. The OSBP will investigate drug diversion and violations of Oregon Administrative Rules (OAR) pertaining to the disposal of pharmaceuticals, including controlled substances. OAR 855-041-0080 directs pharmacies on returned drugs, and states that:

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

(2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;

(a) The drugs or devices are accepted for destruction or disposal and;

(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or

(c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.

(3) Not withstanding section 2 of this rule, drugs or devices previously dispensed or distributed may be returned and re-dispensed or redistributed provided all the following conditions are met:

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.

(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public heath or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing (Oregon Board of Pharmacy 2007).

4.4 Resource Conservation and Recovery Act

The federal Resource Conservation and Recovery Act (RCRA) regulates the transportation, treatment and disposal of hazardous waste. Oregon Department of Environmental Quality (DEQ) operates the RCRA program in Oregon for the U.S. Environmental Protection Agency. With the exception of hospitals, there are few RCRA barriers to a pharmaceutical take back program in Oregon.

Hazardous waste fall into two categories: characteristic wastes and listed wastes. Discarded pharmaceuticals would be regulated as 'listed' hazardous waste if the wastes are listed on either the "P" or "U" lists of the RCRA regulations (see 40 CFR 261.33). To be regulated as a hazardous waste, the P-listed or U-listed ingredient must be the sole active ingredient.

Discarded pharmaceuticals would be regulated as a "characteristic" hazardous waste if the waste exceeded allowable standards for ignitibility, corrosivity, reactivity, and toxicity. For discarded pharmaceutical wastes, the only characteristic that might apply is toxicity. Unwanted pharmaceuticals that have leachable concentrations for selected metals, solvents and some pesticides over toxicity regulatory limits would be regulated as "characteristic" hazardous waste (see 40 CFR 261.24). For example, if leachable barium concentrations in a waste were over 100 milligrams per liter (mg/l) or leachable selenium concentrations over 1 mg/l, the waste would be regulated as a 'characteristic' waste.

Unused pharmaceuticals collected from the resident in a take back program would be considered "household waste", under 40 CFR 261.4 – Exclusions, and as such not regulated under RCRA (U.S. Environmental Protection Agency 2006).Long term care facilities are also not regulated by RCRA – the drugs remain in the official possession of the resident. Depending on their management practices, hospitals may be regulated as a Small Quantity Generator (SQG)[8].

4.5 Mailing of Controlled Substances

A program to collect and dispose of residual pharmaceuticals may include the shipment of residual pharmaceuticals, including controlled drugs listed on Schedules II, III, IV, and V of Title 21, Code of Federal Regulations, -1308.11 to -1308.15. According to the U.S. Postal Service Domestic Mail Manual, which contains the official standards governing domestic mail service, the mailing of controlled drugs is permitted when it is lawful under 21 U.S.C. -801 and 21 C.F.R. -1300 and if the mailer or the addressee is registered with the Drug Enforcement Administration, or is exempt from DEA registration (U.S. Postal Service 2006). Under Title 21 U.S.C. -822(C)(3) a patient who possess a controlled substance by a lawful prescription is not required to register and may lawfully possess the controlled substance (U.S. Drug Enforcement Administration 2002). Thus, the Controlled Substances Act does not prohibit the lawful owner of a prescription medication from mailing it to a law enforcement agency or other DEA registrant for destruction, and 21 C.F.R. -1307.21 allows any person in possession of controlled substances to transfer the drug to a person authorized to posses the drug, such as a law enforcement agency or DEA registrant.

Additionally, the USPS Domestic Mail Manual and Controlled Substances Act regulations specify packaging requirements for the mailing of controlled substances. The controlled substances must be mailed in the original container, with the label intact, in a secure envelope or package that does not indicate the parcel contains a controlled substance (U.S. Postal Service 2006).

[8] The three generator status' under RCRA are Conditionally Exempt, Small Quantity Generator (SQG), and Large Quantity Generator (LQG).

4.6 *Regulatory Uncertainty*

The Safe Drinking Water Act, Title 14 of the Public Health Service Act (42 U.S.C. 300-f-300j- 26) is the key federal law for protecting public water supplies from harmful contaminants (Carter 2006). Deemed too inflexible and expensive, especially for small water suppliers, Congress amended the act in 1996. One of these changes included the establishment of a process for selecting contaminants for regulation. Located in -102(a), the process applies to contaminants that:

(i) may adversely effect human health;

(ii) is known to occur in public water systems with a frequency and at levels of public health concern; and

(iii) in the sole judgment of the Administrator, regulation of such contaminants presents a meaningful opportunity for health risk reduction.

In addition, the Environmental Protection Agency (EPA) should evaluate the availability and costs of treatment techniques to remove the contaminant and assess the impacts of the regulation on the public water systems, economy and public health. Where it is not economically and technically feasible to measure a contaminant at very low concentrations, EPA may establish a treatment technique in lieu of a standard (Carter 2006).

The process of getting a contaminant regulated is long and can be arduous. Every five years EPA must publish a list of chemical or microbial contaminates that meet the requirements set out on section 102(a) (i-iii). This is known as the Contaminant Candidate List (CCL), from which EPA will make a regulatory determination to regulate at least five or more contaminants on the list.

In 2005 EPA published the first CCL and are now in the process of developing the third CCL. According to EPA officials, the third list, to be finalized in 2008, will most likely include a significant number of pharmaceuticals and personal care products (Mannina 2006). The National Research Council has recommended adding pharmaceuticals into the universe of unregulated contaminants (NDWAC 2004).

5 Survey of Drug Take Back Programs

To develop program options, the stakeholder group reviewed several other efforts from within and outside the United States. These included:

- State of Maine's proposed mail back program;
- Clark County Washington's Unwanted Medications Take Back Program;
- San Francisco area Safe Medicine Disposal Days in California;
- Washington State Pilot: Pharmaceuticals from Households: A Return Mechanism (PH:ARM)
- Newberg, Oregon Pilot Project with Long Term Care Facilities;
- British Columbia Medications Return Program;
- San Mateo County, California; and
- State of Iowa.

5.1 State of Maine

The State of Maine is the first state in the United States to pass legislation for the management of unused or expired pharmaceuticals. In 2003, Maine passed Public Law 2003, Chapter 679 which created the Unused Pharmaceutical Disposal Program with the purpose to ensure the safe, effective and proper disposal of unused or expired prescriptions (State of Maine 122nd Legislature 2005). The Maine Drug Enforcement Agency (MDEA) will administer the program (State of Maine Legislature 2004).

The Maine Drug Return Implementation Group was created to develop and implement the program. In March 2005 the Group finished its work and its recommendations included: (State of Maine 122nd Legislature 2005):

- Voluntary drug turn-in events should be conducted by municipalities, community service organizations and law enforcement agencies. Funding for events should come from pharmaceutical manufacturers.
- Due to the state's rural nature, a system to return unwanted drugs by mail should be created with pre-paid envelopes readily available at pharmacies, hospitals, clinics, and law enforcement offices. Mailings, to include both controlled and noncontrolled pharmaceuticals, should go directly to the MDEA. Funding should come from pharmaceutical manufacturers.
- The Maine Legislature should consider legislation to establish a donation program for unused/unneeded pharmaceuticals.
- The MDEA should support an amendment to federal regulations to allow citizens and law enforcement effective methods for disposal of unwanted pharmaceutical controlled substances.

The Maine program was slated to be operational by July 2006, but was delayed due to the lack of funding. In April of 2007, EPA provided Maine a $150,000 grant to pilot, implement,

document, and evaluate their mail-back program. In addition, the pilot will test the effectiveness of an educational campaign about the hazards to life, health, and the environment presented by improper storage and disposal of unused medications.

5.2 *Clark County, Washington*

The Clark County Public Works Recycling and Solid Waste Program administers the program and addresses residents' needs to dispose of both controlled and noncontrolled pharmaceuticals. The Clark County Public Works administers and pays for the program out of its budget. Start up costs consisted of $2,000 for four drop boxes located at four sheriff offices, and $2,000 for brochures (Clark County Solid Waste 2006). Ongoing costs for noncontrolled drugs are absorbed in the Public Works hazardous waste disposal costs and are not tracked separately. For controlled drugs, the sheriff's office absorbs the personnel costs and the disposal costs for the controlled drugs are free.

Residents have the option of dropping off noncontrolled pharmaceuticals at one of 25 participating pharmacies[9], household hazardous waste collection events, or the Central Transfer Station (Clark County Public Works 2006). The pharmacies either ship the pharmaceuticals via FedEx® to the Household Hazardous Waste vendor or has the vendor pick them up. In addition to the general public, veterinarians, medical examiners, and school districts use the unwanted drug return program.

The Free Clinic of Southwest Washington accepts unopened pharmaceuticals in their original packaging as a donation. The clinic does not accept birth control pills, mental health medications, controlled substances, or expired medications.

Residents can take their controlled substances to four different law enforcement locations throughout the area. Each location has a drop off container similar to a US Postal Service postal box. The controlled substances are sealed in a plastic bag and placed into a secured locker until the sheriff's property officers pick them up and transport them to an incinerator for witnessed disposal. See table 5.2 for the amount of controlled drugs collected.

Table 5.2: Clark County Controlled Pharmaceuticals Program Results (Clark County Solid Waste 2006)

TIME PERIOD	PARTICIPANTS	POUNDS COLLECTED
10/01/2003 - 12/31/2003	2	0.04
2004 Calendar Year	4	2.33
2005 Calendar Year	152	7.24
1/1/2006 - 10/31/2006	182	23.08

In the future, Clark County program managers plan to track quantities of collected noncontrolled substances, and work with other law enforcement agencies to establish additional controlled substances collection sites.

[9] List of participating pharmacies found at: http://www.co.clark.wa.us/recycle/Publications/PartPharmacy.pdf

5.3 *San Francisco Area*

Many of the San Francisco area Household Hazardous Waste programs have historically accepted pharmaceuticals at their drop-off stations, but most were forced to stop collecting unwanted drugs due to concerns regarding controlled substances regulations and funding. To deal with the emerging problem of waste pharmaceuticals, the East Bay Municipal Utility District (EBMUD), a municipal utility district that supplies water and provides wastewater treatment for parts of Alameda and Contra Costa counties on the eastern side of San Francisco Bay, organized area wastewater treatment plants to collectively hold 38 collection events outside local Walgreen's pharmacies throughout the region from May 13-21, 2006. The goals of the events were to educate the public, to collect medication, and to conduct the collection events in strict conformance with US Drug Enforcement Administration (DEA) regulations. Prior to the collection events, EBMUD conducted extensive advertising, including radio and print media, flyers, direct mailing, developing a dedicated website, and providing information via a toll-free regional phone line. During the events, pharmacists segregated controlled substances from the noncontrolled with police officers slated to be at each event to handle and remove the controlled substances. The events brought in about 1,500 people with each participant disposing on average of two pounds of pharmaceuticals. The 38 events collected a total of 3,685 pounds of pharmaceuticals, with 9% of the total collected controlled drugs (Jackson 2006).

Over the course of the three days each participant filled out a survey. The survey results showed that 48% of the participants previously disposed of their pharmaceuticals in the trash, while 28% disposed of them in the toilet.Of those that participated in the events, 70% were women, and 57% were over the age of 61. The most successful outreach approaches were through newspapers (35%), flyers (22%) and water bill inserts (13%).

The events turned out to be costly, primarily due to the structure required to deal with the controlled drugs. The total cost was $90,005, which included a waste disposal fee of $3,645, and $86,260 for outreach and advertising. The total does not include the public agency staff time, which required almost 2,000 hours of staff time from 19 participating agencies, or law enforcement officers' time. (Bay Area Pollution Prevention Group 2006).

5.4 *Washington State Pilot: Pharmaceuticals from Households: A Return Mechanism (PH:ARM)*

The Washington State PH:ARM pilot program is an Interagency Resource for Achieving Cooperation (IRAC) team with participants from State Department of Ecology, Board of Pharmacy, Local Hazardous Waste Management Program in King County, Public Health, City of Seattle, King County, Northwest Product Stewardship Council, Snohomish County Solid Waste Management Division, Washington State Department of Social and Health Services-Aging and Disability Services, Washington Citizens for Resource Conservation, Pacific Northwest Pollution Prevention Resource Center (PPRC), Bartell Drugs, and Group Health Cooperative.

The goal of the project is to make disposal as easy as it is to buy the product, and to keep drugs out of the environment. The IRAC team hopes to make it convenient to collect a large volume of pharmaceuticals, and to keep the program financially sustainable and inexpensive. The program will eventually be under the operational control of the Washington State Board of Pharmacy. The project is modeled after the manufacturer provided British Columbia program.

Until it can receive a pilot waiver/exception/exemption from the federal Drug Enforcement Administration to include controlled substances, the program only accepts noncontrolled substances. The program consists of a secured metal drop box located within participating pharmacies where consumers can dispose their noncontrolled pharmaceuticals. The metal containers, which cost about $600 each, are locked steel prototypes and require two keys for access. Inside, a 5-gallon plastic pail is visible through a window slot. When full, the pail is removed, sealed, and shipped to a distribution warehouse. From the warehouse, a reverse distributor/ hazardous waste vendor ships the medication to a high temperature incinerator for disposal. A manifest system provides accountability and tracks the drugs through a written chain of control document.

The pilot PH:ARM program, slated to run from 2006 though 2008, is funded with the support of the Russell Family Foundation, the Public Information and Education fund of the Puget Sound Action Team, Snohomish County Solid Waste Management Division (Coordinated Prevention Grant), King County Water Works, Seattle Public Utilities, Group Health Cooperative, and the Bartell Drug Company. Proposed financing for a statewide system is expected to come from a stewardship model with financing from pharmaceutical manufacturers.

5.5 *Newberg Pilot Project with Long Term Care Facilities*

The City of Newberg, located southwest of Portland in Yamhill County, developed a pilot pharmaceutical take back program for its adult care facilities. In the Newberg pilot, nursing staff at participating adult care facilities discard expired and unwanted pharmaceuticals into "mailbox" type collection containers instead of flushing them down the toilet, which was the earlier practice. Inside the adult care facilities, two collection containers are bolted down in a locked medicine room. The box for controlled substances is locked so that only local law enforcement officials have access. Law enforcement officials retrieve the controlled drugs for witnessed incineration during their regularly scheduled trips to destroy unnecessary/unwanted evidence at an incinerator. A second locked box is used for collection of noncontrolled substances. The garbage collection franchise takes the noncontrolled substances to a household hazardous waste facility using a manifest and chain-of-custody system. The City's Department of Public Works administers and funds the overall project, while local law enforcement pays for the collection and disposal of the controlled substances. Adult care facilities pay a one time cost, about $200, for the secure metal box. The Newberg City Council officially approved the program on March 5, 2007.

5.6 *British Columbia Medications Return Program*

In the 2005 calendar year the British Columbia (BC) Medications Return Program, which has been operational since 1996, collected 39,710 pounds[10], or over 19.9 tons of pharmaceutical waste (Post Consumer Pharmaceutical Stewardship Association 2006). The program is financed and organized by pharmaceutical manufactures through the Post Consumer Pharmaceutical Stewardship Association. Operating in Canada, the BC program is not required to separate controlled pharmaceuticals from noncontrolled as programs do in the US.Based on information gathered at drug take back events held in the United States, which found an average of 9% of collected waste was listed as controlled substances, about 3,574 pounds (1.8 tons) collected may have been controlled pharmaceuticals, under the US system. The program has 844 participating pharmacies located in 131 cities where residents return unused and expired medication.

[10] Number converted from 18,012 kg.

The pharmacist removes the medication from its packaging (except liquids) and the medication is stored in a 20-liter (about 5-gallons) bucket behind the counter. When the containers are filled, the pharmacy faxes a request to the disposal vendor to arrange collection and transport to a secure warehouse. The containers are catalogued and held at the warehouse until a load is adequate for trucking to the incinerator for disposal. During 2005 1,430 containers were collected; an average of 1.7 containers from each participating pharmacy. With the average weight of the containers at 28 pounds, each facility collected an average of 46 pounds annually; of which about 4.3 pounds may have been considered controlled drugs in the United States.

The annual cost of the BC program in 2005 was $190,935.00 (US Dollar)[11]. This equates to a cost of $4.81 per pound. The program is administered by the Post Consumer Pharmaceutical Stewardship Association and funded by pharmaceutical manufacturers selling in British Columbia. The pharmaceutical industry voluntarily established the Medications Return Program (formally called British Columbia EnviRx) in November 1996, and in 1997 regulated it under the BC Post-Consumer Residual Stewardship Program Regulation. This regulation required all brand-owners, which includes the Research and Development, generic, and over-the-counter, manufacturers, of pharmaceutical products sold in BC to provide a way for consumers to dispose of their unused or expired products in an environmentally responsible manner and to take responsibility for the safe management of their products.

5.7 *San Mateo County, California*

Established in September 2006, San Mateo County residents can bring all controlled and noncontrolled pharmaceuticals to ten participating police stations and the county sheriff's office. The pharmaceuticals subsequently are consolidated at the county jail and trucked out-of-state by All Chemical Disposal, Inc. for incineration.

5.8 *State of Iowa*

Since 2004 residents can drop controlled and noncontrolled pharmaceutical drugs at the state household hazardous waste facility, a licensed reverse distributor. The state charges $8.50 per pound for disposal. The local Narcotics Task Force periodically transports the waste pharmaceuticals to an in-state incinerator.

[11] Exchange rate of 0.8486 on January 9, 2007.

6 Oregon Program Options

As of July 1, 2006 the state of Oregon population was 3,690,505; 69%[12] of which live within 241 incorporated cities or towns (Population Research Center 2006). Since Oregon's population is similar to the population served in the British Columbia (BC) pharmaceutical return program, the assumption is that Oregon will return roughly 150% of the BC program of unwanted drugs, 59,565 pounds, with 5,361 pounds of these controlled drugs. The stakeholder group decided at the February 9, 2007 meeting to increase Oregon's return from the BC program due to the large volume of prescriptions, which are usually 30 or 90 day supplies. Due to an accumulation of pharmaceuticals in individual homes, the first few years may experience a higher rate in returns.

Whichever program Oregon chooses, that program will require oversight by the State as this will be more efficient than managing many local programs. This could be a single state agency, a collaborative effort by multiple agencies, or involve an industry stewardship organization to provide and finance a program, as in British Columbia. Potential agencies include: Oregon Poison Center, Oregon Department of Environmental Quality, Oregon Public Health Division, Oregon State Police, and/or the Oregon State Board of Pharmacy. Private partners could include individual companies, a state pharmacy association, or national pharmaceutical associations, which could include research & development, generic, and over-the-counter drug manufactures.

The six program options were researched and estimated costs for the programs researched, including:

1. Installed program – Controlled drugs to taken law enforcement
2. Installed program – Controlled drugs mailed to law enforcement
3. Local law enforcement drop off
4. Oregon State Police mailer
5. Reverse distributor mailer
6. Product stewardship model

The details and estimated costs of each type of program are outlined below.

6.1 Option 1: Installed Program – Controlled Drugs Taken to Law Enforcement

This option would include installing unwanted pharmaceutical drop-boxes in participating pharmacies with controlled drugs being returned to local law enforcement agencies. This option would be permanent, statewide and modeled off the efforts of British Columbia, Clark County, and PH:ARM programs. The program would consist of an estimated 475[13] permanent return centers located at pharmacies throughout the state where residents would drop off their noncontrolled pharmaceuticals with the pharmacists. The pharmacists would place

[12] Determined using state's total population and population within cities and towns.

[13] Based on number of pharmacies in each town/city. Assumes 75% pharmacy participation statewide.

the noncontrolled pharmaceuticals in a 5 or 20-gallon Department of Transportation (DOT) approved container behind the counter. Pick up and disposal costs for a 20-gallon container is estimated to be about $150 each trip[14] (includes cost of the container), compared to a 5-gallon container at an estimated $110[15]. Due to the excessive packaging of medication, use of a 20-gallon container may be the most cost effective, as it will require less pickup and disposal by a hazardous waste contractor. However, storage of the larger containers behind the pharmacy counter could be a problem. If a resident brought in controlled substances, the pharmacist would use a pre-printed flyer to direct them to a drop box located at a local law enforcement office. Based on the current population, there should be an estimated 210[16] local law enforcement drop off boxes.

There two main concerns regarding this option: First, there's a possibility residents may bring in stockpiles of unused pharmaceuticals, which would require the pharmacist's time to sort, as they are prohibited by the Controlled Substances Act to take controlled drugs. Second, residents may be unwilling to make the extra effort to take their controlled substances to a law enforcement drop box. Instead, they may try to leave the controlled drugs at the pharmacy counter, take it home and stockpile it again, flush down the toilet, or throw it in the trash outside the pharmacy.

Table 6.1: Option 1 Estimated program costs - Installed Program – Controlled Drugs Taken to Law Enforcement

ITEM	COST YEAR 1	COST ONGOING YEARS
Supplies		
• 1,550 20-gal DOT approved pails at $25 each. Assume 30 pounds in bucket	$38,750	$38,750
• Flyers: 250 per location at $0.05 each	$5,938	$5,938
• 210 secure metal drop off boxes ($500 each)	$105,000	N/A
• Drop off box cardboard insert boxes (1 each week at 210 locations at $1.00)	$10,920	$10,920
Services		
• Transportation and disposal of noncontrolled drugs 1,550 20-gallon containers	$193,750	$193,750
• Disposal of 2.7 tons of controlled substances: $150 per ton	$405	$405
Labor		
• 2 full time employees ($125,000 year for NRS-4[17])	$250,000	$250,000
• Law enforcement labor. Assume 0.5 hour per pound of controlled at $100,000 annual wage	$128,640	$128,640
Outreach/Communication		
• Estimated	$60,000	$20,000
Miscellaneous (per diem, mileage, photocopies, etc)	$10,000	$10,000
Total	$803,403	$658,403

[4] Cost estimate provided by hazardous waste vendor on 12/15/2006. Actual cost may vary.

[15] Cost estimate provided by hazardous waste vendor on 12/15/2006. Actual cost may vary.

[16] Number assumes one law enforcement drop box per 50,000 people. For example, a town with a population of 150,000 will have three. Towns with populations between 500 – 49,999 will have one box each.

[17] NRS: Natural Resource Specialist.

6.2 *Option 2: Installed Program with Controlled Drugs Mailed to Law Enforcement*

This program would have installed drop boxes at participating pharmacies with controlled drugs mailed to law enforcement. In this program, each pharmacy would have a secured drop box in the pharmacy where residents could drop off their unused noncontrolled pharmaceuticals. A sign on the box would direct residents to talk to the pharmacist if they're unsure whether or not their pharmaceuticals were controlled substances. If they possessed controlled substances, the pharmacist would provide a pre-paid postage envelope the resident could use to mail their controlled pharmaceuticals to a law enforcement agency, such as the Oregon State Police. This process would ensure the resident keeps possession of the controlled substances until it reached a law enforcement agency, keeping the chain of control from owner to law enforcement, as required by the U.S. Controlled Substances Act. At no point would the pharmacy or pharmacist gain control of the controlled pharmaceuticals.

Concern with the program lies with the potential for diversion of the controlled substances for illicit use. Customers with controlled drugs may follow a pattern of dropping the envelope in the same postal service mailbox. If a drug addict were to recognize the pattern, they may attempt to gain access to the USPS mailbox.

Compared to the program without a mailer, this program provides less of a burden on the pharmacy, and greater ease of use to the resident.

Table 6.2: Option 2 Estimated Program Costs - Installed Program with Controlled Drugs Mailed to Law Enforcement

ITEM	COST YEAR 1	COST ONGOING YEARS
Supplies		
• 3,700 DOT approved pail (5 gal) $10 each at 475 locations	$37,000	$37,000
• 4x8 bubble mailer envelopes (10,722) at $0.16 each	$1,716	$1,716
• Pre-paid shipping labels (10,722) at $0.10	$1,072	$1,072
• 475 Secure metal drop off boxes ($600 each)	$285,000	N/A
• Mailing Directions for Controlled (10,722 at $0.05 each)	$536	$536
Services		
• Transportation and disposal of noncontrolled 3,700 5-gallon containers (assume 15 pounds each)	$370,000	$370,000
• Disposal of 2.7 tons of controlled substances: $150 a ton	$405	$405
Postage (10,722 mailers)		
• Business Reply Mail Annual Permit Fee	$160	$160
• Annual Accounting Fee	$500	$500
• Per piece fee ($0.06)	$643	$643
• Parcel Postage ($3.15 per piece)	$33,774	$33,774
Labor		
• 2 full time employees ($125,000 year for NRS-4)	$250,000	$250,000
• Law Enforcement labor - One Full Time Employee at $100,000 per year	$100,000	$100,000
Outreach/Communication	$60,000	$20,000
Miscellaneous (per diem, mileage, photocopies, etc)	$10,000	$10,000
Total	$1,150,806	$825,806

6.3 Option 3: Local Law Enforcement Drop-Off

With this option consumers would drop off their controlled and noncontrolled pharmaceuticals at local law enforcement drop boxes. A drop box could be installed outside, where individuals could drive up and deposit pharmaceuticals, much like a mailbox. A drop box could also be provided inside the law enforcement offices. After separating the controlled drugs from the noncontrolled, law enforcement personnel would handle and witness the destruction of the controlled substances, while the noncontrolled would be shipped out for disposal by a private hazardous waste company.

The major benefit of such a program is the security associated with law enforcement drop off boxes. Concern lays with the availability of local law enforcement personnel to handle the additional work.Additionally, some residents may not feel comfortable bringing their unused medication to a law enforcement office.

Table 6.3: Option 3 Estimated Program Costs - Local Law Enforcement Drop-Off

ITEM	COST YEAR 1	COST ONGOING YEARS
Supplies		
• 210 Secure metal drop off boxes ($500 each)	$105,000	N/A
• Drop off box cardboard insert boxes (2 each week at 210 locations at $1.00)	$21,840	$21,840
Services		
• Transportation and disposal of noncontrolled at $350/55-fiber drum (2x per location)	$147,000	$147,000
• Disposal of 2.7 tons of controlled substances: $150 a ton	$405	$405
Labor		
• 0.5 full time employees ($125,000 year for NRS-4)	$75,000	$75,000
• Law Enforcement labor. Assume 2 hour per week each location at annual rate of $100,000	$1,048,320	$1,048,320
Outreach/Communication	$60,000	$20,000
Miscellaneous (per diem, mileage, photocopies, etc)	$10,000	$10,000
Total	$1,467,565	$1,322,565

6.4 Option 4: Oregon State Police Mailer

Modeled from the state of Maine program, this would involve residents mailing their unused pharmaceutical drugs, controlled and noncontrolled, directly to the Oregon State Police (OSP) for disposal. When a resident visited a pharmacy to pick up a prescription, the pharmacist will offer them a pre-paid postage envelope to mail their residual pharmaceuticals directly to the OSP. The envelope will contain mailing directions, in addition to an educational statement on the importance of proper disposal. After separating the controlled drugs from

the noncontrolled drugs, OSP would handle and witness the destruction of the controlled substances, while the noncontrolled medication will be shipped out for disposal by a private hazardous waste vendor.

Benefits of this program are that it requires minimal time and resources of pharmacies, and it is easy and flexible for the resident, especially for those in rural communities. Additionally, this program would not require an exemption from the U.S. DEA. There is a concern with adding additional responsibilities to the Oregon State Police. One challenge would be reaching those consumers who receive their prescriptions through the mail. This option may also require approval from the United States Postal Service.

Table 6.4: Option 4 Estimated Program Costs - Oregon State Police Mailer

ITEM	COST YEAR 1	COST ONGOING YEARS
Supplies		
• 119,000 4x8 bubble mailer envelopes at 0.16 each - Estimate 0.5 pounds per mailing	$19,040	$19,040
• Pre-paid shipping labels ($0.10 per envelope)	$11,900	$11,900
• Mailing Directions at $0.05 each	$5,950	$5,950
Services		
• Transportation and disposal of noncontrolled substances - 440 55-gal fiber drum with 100 pounds each at $350 each	$154,000	$154,000
• Disposal of 2.7 tons of controlled substances at $150 per ton	$405	$405
Postage (80,000 mailers)		
• Business Reply Mail Annual Permit Fee	$160	$160
• Annual Accounting Fee	$500	$500
• Per piece fee ($0.06)	$7,140	$7,140
• Parcel Postage ($3.15 per piece)	$374,850	$374,850
Labor		
• 0.25 full time employees ($125,000 year for NRS-4)	$31,250	$31,250
• 2 Full Time Law Enforcement Employees at $100,000 per year	$200,000	$200,000
Outreach/Communication	$60,000	$20,000
Miscellaneous (per diem, mileage, photocopies, etc)	$10,000	$10,000
Total	$875,195	$835,195

6.5 *Option 5: Reverse Distributor Mailer*

Similar to the Oregon State Police mailing option, the Reverse Distributor (RD) program would involve residents mailing their unused pharmaceuticals, controlled and noncontrolled, directly to a U.S. DEA registered reverse distributor under contract to the entity operating the Oregon program - - the State or a private entity. A RD is a private business that takes back pharmaceuticals from a business licensed to handle pharmaceuticals, such as a pharmacy or clinic.

The term and category of "reverse distributor" was codified in May 2005 with the amendment of Title 21 Code of Federal Regulations (CFR) 1300.01 (b)(41). The amendments established the regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. RDs must register, provide security, and maintain accurate records for all controlled substances in their possession. As of December 2006 there were 29 RDs registered with the U.S. DEA throughout the United States.

In this program option, when a customer visits a pharmacy to pick up a subscription the pharmacy will offer the person a pre-paid postage envelope to mail their unused pharmaceuticals to a contracted RD. The RD would not sort the controlled from the noncontrolled, but dispose all the pharmaceuticals as if they were controlled substances; this involves a witnessed burn at an incinerator.

The benefits of this program echo those of the direct mailing to the Oregon State Police. Unlike the OSP mailing, implementing the RD mailing program requires an exemption from the U.S. DEA. Yet, the DEA is currently working with the reverse distributor EXP to gain an exemption for a pilot program in the San Francisco area. As of March 2007, it appears an exemption for a pilot program with EXP will go through by the end of 2007. In anticipation, EXP has the facility and processes developed for a instituting a drug return program. Like the previous option, this option would require approval from the United States Postal Office

Table 6.5: Option 5 Estimated Program Costs - Reverse Distributor Mailer

ITEM	COST YEAR 1	COST ONGOING YEARS
Supplies		
• 119,000 4x8 bubble mailer envelopes at 0.16 each - Estimate 0.5 pounds per mailing	$19,040	$19,040
• Pre-paid shipping labels ($0.10 per envelope)	$11,900	$11,900
• Mailing Directions at $0.05 each	$5,950	$5,950
Services		
• Reverse Distributor costs - $0.70 per pound for all pharmaceuticals	$41,696	$41,696
Postage (80,000 mailers)		
• Business Reply Mail Annual Permit Fee	$160	$160
• Annual Accounting Fee	$500	$500
• Per piece fee ($0.06)	$7,140	$7,140
• Parcel Postage ($3.15 per piece)	$374,850	$374,850
Labor		
• Full time employee ($125,000 year for NRS-4)	$125,000	$75,000
Outreach/Communication	$60,000	$20,000
Miscellaneous (per diem, mileage, photocopies, etc)	$10,000	$10,000
Total	$656,236	$566,236

6.6 *Option 6: Product Stewardship*

This option would utilize an industry stewardship organization to finance and provide the program, such as the Post Consumer Pharmaceutical Stewardship Association's (PCPSA) Medicine Return Program in British Columbia. PCPSA is a not-for-profit industry sponsored organization that manages product stewardship initiatives for pharmaceutical and self-care products on behalf of its members across Canada. Organizations that fulfill similar functions can also be referred to as producer responsibility organizations, industry funded organizations, or third party organizations. They are common in Europe and throughout Canada for financing and providing the collection of a wide range of products including pharmaceuticals, automotive fluids, batteries, electronics, paint, pesticides, solvents, tires and other products. In the U.S., examples include the Rechargeable Battery Recycling Corporation (RBRC 2006) and the Thermostat Recycling Corporation (NEMU 2007), both of which have been established by manufacturers voluntarily.

A similar system was created in Oregon for electronic waste with the passage of the Oregon Electronics Recycling Law, House Bill 2626 (2007 Session). This bill creates and finances a statewide collection, transportation, and recycling system for televisions, desktop and portable computers, and computer monitors in Oregon. The system is financed by manufacturers.

Additional stewardship organizations are currently under development in the U.S. to address carpet and paint.

Developed by legislative mandates, or reached through negotiations and Memoranda of Understandings, stewardship organizations typically provide a plan to the government of how the responsible manufacturers will collectively provide the required services, meet targets and provide annual reports.

Stewardship organizations finance and establish collection and processing services on behalf of their membership voluntarily, or to comply with legislative mandates. The Stewardship Organization's membership and board of directors determine how the program is financed. Since there are many program options, the private sector often selects the programs that are most equitable to their members, easily assessed and collected to the residents, with minimum bureaucracy. Examples of options include fees based on size of company, annual sales, individual product sales (such as number of prescriptions), and percent of returned product. Many industry trade organizations have tiered membership fees based on industry-relevant and accepted criteria.

In the case of PCPSA, prescription (name brand and generic) and over-the-counter ("self-care") manufacturers are billed for the cost of the Medicine Return Program and its administration. There is a minimum charge of $200 per year. Manufacturers of "self-care" drugs are charged $0.25 per $1,000 of product sold in British Columbia. Manufacturers of prescription drugs are billed a fee based on the number of prescriptions filled in British Columbia[18].

This option keeps the program financing directly related to the producers, users and disposers of medications. Since financial decision making remains in the control of the private sector, it could result in equitable and efficient fee assessment while minimizing government bureaucracy. While a stewardship organization could be established voluntarily, more likely a legislative mandate would be required.

6.7 *Summary of Oregon Program Option Cost Estimates*

Tables 6.7a and 6.7b compares and summarizes the five Oregon program options. Table 6.7a lists year one costs only, while table 6.7b lists ongoing annual costs. It is important to note that the first year's costs are generally higher due to costs associated with program start-up. The product stewardship option is not listed on the summary, as the stewardship organization would have to develop and finance the program.

[18] The Medicine Return Program stewardship plan and annual reports available at *http://www.medicationsreturn.ca/british_columbia_en.php*

Table 6.7a: Summary of Year One Cost Estimates

	OPTION 1 INSTALLED - CONTROLLED TAKEN TO LAW ENFORCEMENT	OPTION 2 INSTALLED - CONTROLLED MAILED TO LAW ENFORCEMENT	OPTION 3 LOCAL LAW ENFORCEMENT DROP OFF	OPTION 4 OSP MAILER	OPTION 5 REVERSE DIST. MAILER
Supplies	$160,608	$325,324	$126,840	$36,890	$36,890
Services	$194,155	$370,405	$147,405	$154,405	$41,696
Postage	NA	$35,078	NA	$382,650	$382,650
Labor	$378,640	$350,000	$1,123,320	$231,250	$125,000
Outreach	$60,000	$60,000	$60,000	$60,000	$60,000
Miscellaneous	$10,000	$10,000	$10,000	$10,000	$10,000
Total	$803,403	$1,150,806	$1,467,565	$875,195	$656,236

Table 6.7b: Summary of Ongoing Cost Estimates

	OPTION 1 INSTALLED - CONTROLLED TAKEN TO LAW ENFORCEMENT	OPTION 2 INSTALLED - CONTROLLED MAILED TO LAW ENFORCEMENT	OPTION 3 LOCAL LAW ENFORCEMENT DROP OFF	OPTION 4 OSP MAILER	OPTION 5 REVERSE DIST. MAILER
Supplies	$55,608	$40,324	$21,840	$36,890	$36,890
Services	$194,155	$370,405	$147,405	$154,405	$41,856
Postage	NA	$35,078	NA	$382,650	$382,650
Labor	$378,640	$350,000	$1,123,320	$231,250	$75,000
Outreach	$20,000	$20,000	$20,000	$20,000	$20,000
Miscellaneous	$10,000	$10,000	$10,000	$10,000	$10,000
Total	$658,403	$825,806	$1,322,565	$835,195	$566,396

6.8 *Summary of Programs Benefits and Burdens*

Of the program options explored by the stakeholder group, each have certain benefits and burdens. Table 6.8 summarizes and compares these.

Table 6.8: Summary of program benefits and burdens

PROGRAM OPTION	BENEFITS	DRAW BACKS
Pharmacy collection of noncontrolled medication – controlled drugs to law enforcement	- Pharmacy drop off convenient for public - Permitted under existing Drug Enforcement Administration (DEA) regulations	- Added burden for law enforcement agencies - Pharmacist's time to sort controlled from noncontrolled drugs
Pharmacy collection of noncontrolled medication with mail back of controlled drugs to law enforcement	- Pharmacy drop off convenient for public - Allowable under existing DEA regulations - Mail back convenient for hospice personnel	- Expensive to establish and operate - Added burden for law enforcement - Pharmacist's time to sort controlled from noncontrolled drugs
Collection of all pharmaceuticals (controlled and noncontrolled) at law enforcement agencies	- Permitted under existing DEA regulations	- Not convenient for public - Likely low participation - Burden on limited local law enforcement personnel
Mail back of all pharmaceutical drugs to Oregon State Police	- Allowable under existing DEA regulations - Convenient for public - Relatively low cost to establish	- Diverts resources from primary Oregon State Police mission
Mail back of all drugs to Reverse Distributor	- Convenient for public - Controlled and uncontrolled mailed together - Cost effective - Easy to expand to include long term care facilities, hospice, vets, etc. - Business interest	- Waiver from the US Drug Enforcement Administration required - Need cooperation and financial contract with commercial entity
Product Stewardship program	- Industry organized, funded and administered - Efficient - Little/no government involvement - Could be model for other parts of nation	- Depends on industry to voluntarily organize and fund program

7 Subgroup Findings

The three subgroups were formed out of the larger stakeholder group with the purpose of determining the ideal take back programs for adult care facilities, hospitals, and the general public.

7.1 Adult Care Facilities – Program Design Suggestions

7.1.1 SUBGROUP MEMBERSHIP

- Brenda Bateman, Tualatin Valley Water District
- Jane Thompson, City of Springfield
- Marney Jett, Clean Water Services
- Mike Dingeman, Oregon State Police
- Tom Penpraze, City of Corvallis
- Dave Stitzhal, Northwest Product Stewardship Council

7.1.2 OVERVIEW

In the summary below, the subgroup has included some basic information about adult care facilities in Oregon, some key considerations affecting recommendations, and then the recommendations themselves. In addition, the subgroup noted that two types of adult care facilities -- home hospice and adult foster care -- do not fit into comfortably into the recommendations outlined, because of their number and staffing structure.Special attention will need to be given to serve these adult care facilities.

7.1.3 ADULT CARE FACILITIES – BASIC INFORMATION

Numbers and Definitions. The subgroup limited the definition of "adult care facilities" to residential care, assisted living, and nursing homes. In Oregon, there are 573 adult care facilities with the capacity to serve almost 35,000 individuals. See detailed descriptions in Figure 7.1.3. In addition, Oregon has residential facilities for children and adults with developmental disabilities.

Figure 7.1.3.Adult Care Facilities in Oregon (as of March 2007)

CATEGORY OF CARE	DESCRIPTION	NUMBER OF FACILITIES IN OREGON	NUMBER OF PATIENTS IN OREGON (AT MAXIMUM CAPACITY)
1. Residential Care Defined in OAR 411-055-0000(33)	Homes for six or more people. Some offer private rooms and registered nurse consultation services.	230	8,674
2. Assisted Living Defined in OAR 411-056-0005(5)	Homes with six or more private apartments. Physical care and additional health care supervision and assistance are available.	201	13,519
3. Nursing Homes Defined in OAR 411-085-0005(37)	Nursing care on a 24-hour basis in a hospital-like setting with skilled care, rehab, and end-of-life care. Appropriate for people who need a more protective setting because of medical and behavioral needs.	142	12,495
TOTALS		573	34,688

Current Protocols. The Oregon Department of Human Services licenses each of these facilities, and has regulatory authority over their operations. Typically, the nursing staff in each of these facilities is responsible for disposing of unwanted or leftover medications. At the time of disposal, the nursing staff documents the name of each medication, dosage strength, whether it is in liquid or solid form, and the amount remaining. These medicines are then flushed down the drain. A take-back program would dispose of these pharmaceuticals in a more environmentally responsible manner.

For facilities that provide services for the developmentally delayed, OAR 411-325-0120 requires those facilities to have in place policies to deal with the disposal of unused controlled and noncontrolled medication (Oregon Department of Human Services 2004).

Reducing the Amount Disposed. Oregon is one of several states whose Board of Pharmacy allows adult care facilities to send unused noncontrolled substances back to contract pharmacies if certain conditions are met. If they do not already do so, adult care facilities should return as many noncontrolled substances as they can to their "consultant" or "contract" pharmacies, reducing the overall volume destined for disposal. Most adult care facilities in Oregon use consultant pharmacies.

Oregon Administrative Rules (OAR) 855, Division 41 allows pharmacies to re-dispense noncontrolled drugs if the drugs:

1. Are in an unopened, tamper-evident unit (i.e., bubble packs);
2. Remained under the control of a person trained in the storage and administration of drugs in long-term care facilities using the services of a consultant pharmacist;
3. Have not been adulterated or misbranded; and
4. Have been stored under conditions meeting U.S. Pharmacopoeia standards.

7.1.4 KEY CONSIDERATIONS

There are several characteristics of adult care facilities that will have a profound effect on any take-back program, including:

- Having staff transport controlled substances to law enforcement facilities is a problem, because the prescriptions would not be in their names.
- There would be a higher percentage of controlled substances in these collections than in the general public because many noncontrolled substances can go back to the pharmacy for re-dispensing.
- Currently, destroyed medications are sorted (controlled vs. noncontrolled) and well documented before disposal by flushing.
- Only assisted living and nursing homes must have a locked medicine room on site. Residential care facilities must have a "secure system" in place for the storage of pharmaceuticals.
- Any mail-back program would require adult care facilities to use larger boxes or more frequent mailings than household participants.

7.1.5 PREFERRED MODEL

Using a locked medicine room with a locked collection container is the preferred model, primarily because using household-size envelopes in a mail-back program would be time consuming, while using larger boxes would require nursing staff to store and have access to controlled substances for relatively long periods of time[19].

The sub-group believes that given the volume and concentration of controlled substances, it would be best to have someone visit each facility to collect the unwanted pharmaceuticals. The best option would be a Reverse Distributor who could collect all categories of medicine at once and then take everything to an approved hazardous waste incinerator without further sorting or inventorying anything.Use of a private reverse distributor would require an exemption from DEA.

Failing that exemption, law enforcement could first collect all pharmaceuticals and then contract with a reverse distributor to haul the items to a hazardous waste incinerator out-of-state. This is the model currently in use in San Mateo County and City of Vacaville, Calif.

If this still remains unacceptable to DEA, the sub-group's preference would be to follow the model established by the City of Newberg, Oregon. See section 5.5 Newberg Pilot Project with Long Term Care Facilities, for details.

Adult care facilities could be required to participate in drug take-back programs as part of the accreditation requirements from the Oregon Department of Human Services – see OAR Division 411.

7.1.6 EDUCATION AND OUTREACH PROGRAMS

Outreach for the long-term care facilities portion of an Oregon Drug Take Back Program would be multi-tiered. Broad publicity for the program could be placed in industry newsletters (such as AARP, nursing associations, and other membership organizations)[20]. The Oregon Department of Human Services could publicize the program in a more direct manner, given its regulatory oversight and record-keeping responsibilities.

Hands-on training at each site would be crucial, as the program would be set up in each facility. A training program should include hard-copy protocols and reference materials, as well as leave-behind posters and decals in each med room. These materials would reinforce program requirements and emergency / informational contact information. A reverse distributor could provide an even better means of reaching all the long-term care facilities in Oregon.

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[19] A mail-back program would ship all collected materials (without the need to sort) to a pharmaceutical waste disposal facility, such as EXP Pharmaceutical Waste Management located in California. The allowable size of the parcels is dependant on regulations set by the Department of Transportation and varies from state to state. Shipments to California are further restricted by the Medical Waste Management Act, which categorizes materials collected through pharmaceutical take-back programs as medical waste. Currently, EXP accepts parcels through UPS weighing no more than sixteen pounds as set by the MWMA.

Ultimately, the parcel size and labeling requirements will be dependant on the method of shipping. Provided the collected materials are non-hazardous, the only restriction imposed by the United State Postal Service is a 70-pound limit per parcel. Delivery services, such as FedEx, require that all local, state, and federal laws are followed and recommend a signature upon delivery. Parcels sent through FedEx must not have any labels, markings, or other written notice that a pharmaceutical is contained inside.

[20] Some key outreach contacts include: 1) Elaine Young from the Oregon Dept. of Human Services; 2) Ruth Gulyas, Executive Director of Oregon Alliance of Senior & Health Services; and 3) Jim Carlon, Executive Director of Oregon Health Care Association.

Also, any Oregon drug take back program should partner with the consultant/contract pharmacies to help reach out to the adult care facilities. A key common message should be broadcast to all long-term care facilities from pharmacies, ***"Return all eligible drugs to your contract pharmacy. To dispose of any remaining drugs, please do the following."***

7.2 *Hospitals: Drug-Take Back Needs and Opportunities*

This section summarizes the initial findings of the Hospital subgroup's assessment of the management of pharmaceuticals in hospitals, and provides recommendations for next steps in gathering additional information and designing possible programs to ensure pharmaceuticals are managed properly in hospitals. The primary focus is on in-patient hospital pharmacies, rather than the retail pharmacies residing in some hospitals that serve the general public.

7.2.1 TEAM MEMBERS

- Kevin Masterson, DEQ
- Jim Hill, City of Medford
- Gerry Migaki, Providence Health Systems

7.2.2 INITIAL ASSESSMENT OF MANAGEMENT OF PHARMACEUTICALS IN HOSPITALS

Information on the current management of pharmaceuticals in hospitals was obtained from a team member who manages a hospital pharmacy and through interviews with a few other hospital pharmacy representatives. This information was used for an initial assessment of the status of pharmaceutical management in hospitals. The principal finding from the assessment was that most hospitals have comprehensive procedures in place to recover leftover drugs, thus minimizing the discharge of pharmaceuticals to the sanitary sewer or disposal into the solid waste system.

Many hospitals implement the following practices to ensure proper management of leftover or outdated drugs:

- Dispense drugs through a "unit dosing" procedure, which involves providing the patient with only a single dosage of a drug when it's needed (e.g., individually wrapped pills). This procedure also allows reuse of medication, thus minimizing waste.
- Outdated drugs or unusable drugs are either returned to the inpatient pharmacy by hospital staff or removed from stock by pharmacy staff. Only return of narcotics requires a double signature process. The pharmacy then contracts with a Reverse Distributor to take unused drugs that are in solid form. Liquid drugs cannot be as readily reused, thus are not typically managed through the Reverse Distributor.
- Utilize contracts with hazardous waste disposal firms to manage drug wastes that are classified as RCRA hazardous waste, or other pharmaceuticals that cannot be taken by the Reverse Distributor.
- Provide training and education to hospital staff that handle drugs to ensure they follow proper management protocols.

If these practices are widely implemented in hospitals throughout Oregon, the Hospital subgroup believes there would be little our no need for additional programs to improve pharmaceutical management to protect the environment and public health. However, there may be gaps in the existing management systems at some hospitals. The sections below summarize these potential needs and how they will be identified and addressed.

7.2.3 POTENTIAL GAPS IN CURRENT HOSPITAL PHARMACEUTICAL MANAGEMENT

To verify whether improvements are needed in existing pharmaceutical management systems in hospitals, information needs to be obtained from hospitals that were not contacted as part of the initial assessment. Additional information may also need to be collected from hospitals that have already interviewed. The possible gaps that were identified include:

- **Small Hospitals** - The hospitals contacted for the initial assessment were large and medium facilities or health systems. It's possible that small community hospitals may not have the resources to implement the best management practices followed by the larger hospitals.
- **Use of Sharps Containers** – In some hospitals it was acknowledged that drugs occasionally get disposed of into sharps containers. This could pose the potential risk of theft.
- **Proper Disposal of Non Prescription Drugs** – Unused nonprescription drugs are handled like prescription drugs in the hospital.
- **Drugs Brought into Hospitals** - Although most hospitals have policies that prohibit or discourage patients from bringing in their previously prescribed drugs, it may not be practical for hospitals to ensure all of these personal supplies are prevented from entering the hospitals.All hospitals have a process in place for control of these medications when used within the hospital (Joint Commission requirement). Since these medicines are not the property of the hospital, they need to be sent home with the patient on discharge or disposed of through the hospital disposal channels on approval by the patient.
- **Liquid Drugs** – As mentioned previously, liquid drugs are not as reusable as solid drugs and, therefore, cannot be taken by the Reverse Distributor. Some of these liquids – such as chemotherapy drugs – may be considered RCRA hazardous wastes, while others are not regulated by RCRA. If unit dosing practices are followed, there may not be large quantities of these liquids generated. However, there does not appear to be a consistent management system for the liquid drug wastes that are generated, especially those that are not required to be managed as hazardous waste.
- **Personnel Training and Education** – Hospitals are complex facilities with multiple units operating somewhat autonomously. Thus, ensuring that all personnel who come into contact with leftover or unused pharmaceuticals follow established procedures is a challenging task. There may be instances where most, but not all, hospital personnel are returning drugs to the in-patient pharmacy or other designated central collection point.

7.2.4 RECOMMENDED NEXT STEPS

The objective of the hospital subgroup was to collect additional information from hospital pharmacy representatives in the state, determine whether gaps exists, and then provide assistance or resources to hospitals to address those gaps. The subgroup recommended the following actions:

- **Develop and Distribute a Survey to Oregon Hospital Pharmacies** – The sub-group recommends partnering with the Oregon Association of Hospitals and Health Systems (OAHHS) in developing and distributing an anonymous survey of hospital pharmacies statewide. OAHHS represents the vast majority of hospitals and health systems in the state, and their participation in the survey will help to maximize the response. The specific sub-tasks include:
- Team develops draft survey;

- Contact OAHHS public affairs manager about partnering on survey (if possible, set up a face-to-face meeting);
- Finalize survey with assistance from OAHHS and Oregon Society of Health System Pharmacists (OSHP);
  - Obtain a list of hospital pharmacy directors at OAHHS member hospitals
  - OAHHS distributes survey; and
  - Partners review and evaluate survey results.
- **Pharmaceutical Management Technical Assistance Options** -- If the assessment of the survey results reveals obvious gaps in the management of pharmaceuticals at hospitals, or a subset of hospitals, the subgroup may develop and provide certain types of informational resources and technical assistance. Depending on the needs identified, some assistance could be tailored to individual facilities, while other efforts may be targeted at all hospitals and delivered through OAHHS and the OSHP. Designing a new drug take back program for hospitals is not one of the possible options, given the existing resources and systems available to hospitals. The level and type of assistance offered would be determined, in part, by the involvement of OAHHS and OSHP and other potential partners, but could include:
  - Providing information on Reverse Distributors to hospitals that don't have contracts with such entities.
  - Develop and distribute fact sheets and personnel training resources that outline the importance of proper drug waste management and local hazardous waste management service providers. A comprehensive list of drug wastes that are considered RCRA hazardous wastes could also be provided.
  - Assist small hospitals (which are RCRA conditionally exempt generators) in developing a partnership whereby they can "pool" their pharmaceutical wastes and share the costs of management and disposal.
  - Research available options for managing liquid drug wastes and other pharmaceutical products that don't have readily available management systems (e.g., radioactive iodine, "contrast" agents, etc.).
  - Facilitate peer-to-peer contacts, so that smaller hospitals with limited resources can benefit from the experiences and knowledge of the larger hospitals.

7.3 *Hospice*

Within Oregon, there are 66 hospices, which provide palliative services to terminally ill patients and support for their families. Four of the hospices operate facilities, in addition to providing home care: two have hospice residences, licensed as foster homes, and two have inpatient hospices, licensed as specialty hospitals. The majority of hospice patients die in their own home (53%); 40% die in community-based long term care facilities; 5% die in inpatient hospices, and less than 2% in hospitals. Approximately 1% die in a nursing facility after being admitted by hospice. In Oregon about 30,000 people die a year, of which between 60% to 70% occur under hospice care.

Since hospices use a (relatively) large amount of controlled substances for pain and symptom management, hospice personnel are often on the "front line" of medication disposal. Hospice purchases and provides all the medication related to the terminal illness, and many patients also have unrelated medications. The hospices that are affiliated with a hospital or medical center

typically purchase the medication through their pharmacy. Other hospices may use local pharmacies, such as Wal-Mart and Fred Meyer, but many are shifting towards using mail order pharmacies, such as Hospice Pharmacia.

Hospices are required to have policies for the disposal of medications, most of which include an offer to dispose of unwanted medicines for the family, typically by flushing them down the toilet in the patient's home. This is the only viable disposal technique, as hospice personnel cannot remove any drugs from a home. The families have a right to refuse the drug disposal service; in this case, the hospice will document that the family retained the remaining drugs. Some hospices have reviewed the new federal medication disposal recommendations, but overall there appears to be a reluctance to carry and provide the tools necessary for disposal, such as kitty litter.

For hospice settings, especially for in-home care, a tamper-proof mail back program would be the preferred solution to disposal. There may be potential to leverage some funding from hospice mail order pharmacies as part of their promotional campaigns. Rarely, chemotherapy drugs may be used in a hospice setting; as some chemotherapy drugs are considered hazardous materials, the current policy for their disposal should stay intact.

7.4 Public Group

The public group was unable to provide a report.

8 Oregon Program Funding Options

8.1 Oregon Program Funding: Year one

The first year of the chosen program will involve start up costs associated with required infrastructure and outreach, in addition to costs associated with running the program. For example, if secured drop-off bins in 475 pharmacies around the state is the preferred program, the costs for the bins are estimated at $600 a piece, at a total cost of $285,000. Public outreach and controlled substances mailing materials will cost an additional $62,875. Ideally, funding for the infrastructure for the first year could come from the pharmaceutical industry, as well as grants and donations. Due to the social and environmental impacts caused by unwanted pharmaceutical disposal, there may be an opportunity to secure grants for part of the start up program costs. An inventory of organizations that might be potential grant targets is located in Appendix D.

8.2 Oregon Program Funding: Ongoing years

A variety of funding options were explored. While preferred, funding does not need to come from one source alone; funding can come from multiple sources.

8.2.1 OPTION 1: SOLID WASTE DISPOSAL FEE

The Oregon Department of Environmental Quality's (DEQ) Solid Waste Program receives all of its funding from permit fees charged to disposal facilities and from disposal fees charged on each ton of waste disposed of in municipal landfills, incinerators, energy recovery facilities, and industrial landfills. Out-of-state waste disposed in Oregon and Oregon waste shipped out-of-state for disposal are also subject to Oregon ***disposal*** fees, but not ***permit*** fees. Under Oregon Revised Statute (ORS) 459.235[21], the permit fee is $0.21 per ton of solid waste for municipal landfills, construction landfills, off-site and captive industrial facilities, sludge disposal facilities, incinerators and solid waste treatment facilities. Energy recovery facilities pay a $0.13 per ton permit fee. In addition to the $0.21 per ton, the Recycling Act permit fee of $0.09 is added; this fee applies to solid waste facilities except for transfer stations, material recovery facilities, composting facilities, and captive industrial facilities.

Under ORS 459A.110[22], DEQ can assess fees for programs for reduction of domestic solid waste and environmental risk. ORS 459.110(2) states that, ***"... the fee is to be based on the estimated or actual tonnage received at the site or transported out of state for disposal and any other similar or related factors the commission finds appropriate."*** But, ORS 459A.110(7) states that fees shall be no more than $0.50 per ton per disposal fee. Currently there are two separate disposal fees, one for $0.31 per ton and the second at $0.50 per ton, for a total of $0.81 per ton.

[21] For a full listing of ORS 459 go to http://www.leg.state.or.us/ors/459.html.

[22] For a full listing of ORS 459A go to http://www.leg.state.or.us/ors/459a.html.

As of January 2007 the disposal fee under ORS 459A.110 of $0.81 per ton solid waste applies to all disposal sites except transfer stations and to entities that transport solid waste out-of-state for disposal. DEQ primarily uses this fee to:

- Provide household hazardous waste programs;
- Implement programs to promote and enhance waste reduction and recycling statewide, including data collection, performance measurement, education and promotion, market development, and demonstration projects;
- Monitor groundwater and enforce groundwater protection standards at disposal sites that receive domestic solid waste;
- Help counties and metropolitan service districts plan solid waste disposal programs, including closure of disposal sites;
- Provide technical assistance and grants to local governments for recycling and solid waste planning activities;
- Periodically study solid waste composition; and
- Pay DEQ administrative and other costs related to providing solid waste prevention, reduction, and safe management programs.

In 2005 4,799,042 tons of municipal waste was disposed of in Oregon landfills, of which 1,795,971 originated from out of the state and 3,003,071 originated in-state. The in-state disposal rate represents about 1,667 tons per capita. In all, 6,067,742 tons of solid waste (includes municipal, asbestos, tires, sludge, industrial, ash, contaminated soils, and alternate daily cover) were disposed of or exported out of Oregon.

If a pharmaceutical disposal fee were assessed on both in and out-of-state municipal waste an additional fee of $0.17 per ton of waste would be required to finance a program cost of $800,000[23]. This would raise the disposal fee from $0.81 per ton to $0.98 per ton.

A second option is to assess a disposal fee to all Oregon disposed and exported wastes (excludes materials used for alternate daily cover) for a total of about 6,006,933 tons a year. Financing an $800,000 program would require an additional $0.13 per ton fee. This would raise the municipal waste the disposal fee from $0.81 to $0.94 per ton; and raise the permit fees on the other wastes from $0.21 to $0.34 per ton.

Oregon Administrative Rule (OAR) 340-097-0120 (3)[24] states that any increase in the Solid Waste Permit and Registration Compliance Fee base rates must be fixed by rule by the Environmental Quality Commission (EQC). Operators of solid waste disposal sites, both private and municipally-owned, are opposed to solid waste tipping fee increases that don't fund solid waste programs. A concern is that the addition of another statewide fee could make it harder for a disposal site to increase fees to fund local programs. As tipping fee increases in Oregon are passed on to the local solid waste collection programs, most cities and counties set the collection program rates. Thus, any increase must first go through a rate review discussion and then voted on by the city council or county commission. Additionally, rate pressure is an issue for solid waste and recycling collection programs; a fee increase to fund drug take back programs could make it harder to raise rates need to fund future local communities solid waste and recycling collection programs.

[23] Based on DEQs 2005 solid waste disposal data.

[24] For full listing of OAR 340 go to *http://arcweb.sos.state.or.us/rules/OARs_300/OAR_340/340_097.html*.

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The benefit of this option is it removes the pharmaceuticals from landfills, and spreads the costs around the state, to both rural and urban. Additionally, the more waste a household generates the more it will have to pay. As noted, the landfill operators would oppose such a funding scheme. An additional disadvantage of the program is it will require at least an administrative rule change by the Environmental Quality Commission and legislative authorization. Additionally, the funding may have to compete with other worthy special waste programs around the state.

8.2.2 OPTION 2: PHARMACEUTICAL FEES

Oregon Revised Statute (ORS) 689.135[25] regulates the State Board of Pharmacy's power to assess fees and the approved use of those fees. According to ORS 689.135(7), fees collected go to the State Treasury and are placed at the credit of the State Board of Pharmacy to be used only for administration and enforcement of ORS 435.010 to 435.130[26]. The U.S. Controlled Substances Act and the enforcement of ORS 689 (The Oregon Pharmacy Act) regulate the states pharmacists, drug outlets, and sales. The fees that may be collected by the Board are listed in Oregon Administrative Rules (855-110[27]) as well as in Statute (ORS 689.135). Fees are listed in OAR 855-110-0005 and broken down into categories of licensing; registration, renewal, and re-inspection of drug outlets; registration for controlled substances; and administrative. Total cost of fees will vary on the number of pharmacists, technicians, etc. at a facility, but the average fees per pharmacy per year are about $1,500. Wholesalers, manufactures, and reverse distributors pay annual fees approximately $400 a year, plus an additional $50 if they handle controlled substances.

As of January 2007 there were 1,091 retail pharmaceutical drug outlets (includes mail order), 268 manufacturers, 579 wholesalers with prescription licenses (includes reverse distributors), and 63 non-prescription wholesalers licensed in Oregon. Each facility would have to be assessed a fee of $400 per year to cover an $800,000 pharmaceutical drug return program. The fees could be imposed on one set of Board of Pharmacy registrants and not others. The costs of putting the entire fee just on the pharmaceutical drug outlets would be an estimated additional cost of $733 per year. If the costs were split between the manufacturers, and wholesalers, the fee would be an additional $879 per business.

The process to assess fees for a pharmaceutical drug return program would require a legislative change to ORS 689.135. The fee and its use would have to be included in OAR 855-110. Additionally, this option would require support from the Board of Pharmacy.

The benefit of this funding option is it would essentially assess a tax on pharmaceutical users for their pharmaceutical waste. An equity issue is the downside, as the fee would initially tax current users for the disposal costs of previous pharmaceutical users.

[25] Full listing of ORS Chapter 689 found at http://www.leg.state.or.us/ors/689.html.

[26] OAR 435 located at http://www.leg.state.or.us/ors/435.html.

[27] http://arcweb.sos.state.or.us/rules/OARS_800/OAR_855/855_110.html.

[28] Full listing of fees located at http://arcweb.sos.state.or.us/rules/OARS_800/OAR_855/855_110.html.

8.2.3 OPTION 3: MIX OF SOLID WASTE DISPOSAL AND PHARMACEUTICAL FEES

A third option is to split the costs between a solid waste disposal fee and a pharmacy fee, essentially a blend of the first two options.For an $800,000 program, $400,000 would come from a solid waste disposal fee and $400,000 from a pharmacy fee. The costs to the retail pharmaceutical drug outlets, manufacturers, reverse distributors and wholesalers would be an annual fee increase of $206. The fee increase for municipal solid waste disposal would be an additional $0.08 per ton.

This option would spread the program costs among pharmaceutical users and those who generate solid waste. This program would require legislative approval and a change in the Oregon Administrative Rules.

8.2.4 OPTION 4: STATE GENERAL FUND

The program could be funded by a general fund appropriation from the Oregon Legislature. Prior to approaching the Oregon Legislature for funding, the stakeholder group would need determine the preferred program option and determine the preferred agency or agencies to administer the program.

8.2.5 OPTION 5: SURCHARGE ON WASTEWATER OR DRINKING WATER UTILITIES BILLS

This option would place a surcharge on either wastewater (sewer) utility, and/or drinking water utility bills. In Oregon, there are 3,617 public water systems of which 893 are community water systems serving 2.5 million people. There are 343 non-transient, non-community systems (schools, factories, and commercial businesses), 1,470 transient, non-community systems (campgrounds and rest areas) and 911 state-regulated systems (small subdivisions and mobile home parks)[29]. According to the Public Utility Commission, as of February 20, 2007 there were 30 rate and service companies and 49 service only regulated water companies. Of the 30 rate and service regulated companies, two were both a water and wastewater company. Costs of a pharmaceutical drug return program could be equitably shared on per person served among the 893 community water systems, and the 911 state regulated community water systems. The fee for an $800,000 program, with 2.5 million water users, would be about $0.32 a year per user.

The benefit of this program is that the 2.5 million uses of community drinking water systems would share the costs throughout the state; no one area would shoulder the burden. Yet, those residents who are off the community systems, those who have wells and septic systems, would not financially contribute to the program, but would receive services. Though most Oregonians are served by a municipality, this funding option would require approval from the Public Utility Commission to include the regulated utilities. The collected fees would need to be transferred from each utility to the program administrator.

8.2.6 OPTION 6: PER PRESCRIPTION FEE

This option would place a per prescription fee on each prescription filled in Oregon to finance the program. According to the Kaiser Family Foundation (2007), in 2005 there were 33,473,641 retail prescription drugs filled at pharmacies in Oregon, with an average cost of $53.00. Financing an $800,000 program would require a fee of $0.024 per prescription. This figure does not include the administrative costs required to collect the fees.

[29] Further information at *http://oregon.gov/DHS/ph/dwp/about_us.shtml*.

As of July 2007, Oregon does not have a system in place to accurately track prescriptions sold or to collect the fees, therefore a system would have to be developed before implementation. The burden of administrating the system might fall to the Oregon Board of Pharmacy and require legislative approval.

The benefit of this option is it would place the burden of financing the program on the purchasers of pharmaceuticals. Yet, this may also place the burden on those who can least afford it, such as those on a fixed-income. The administrative costs to collect the fee would be substantial.

8.2.7 OPTION 7: PRODUCT STEWARDSHIP

As explained in further detail in the product stewardship program option, located in section 6.6, this option would utilize an industry stewardship organization to finance and provide the program. This option keeps the program financing directly related to the producers, users and disposers of medications, and keep the financial decision-making in the control of the private sector. The downside is that while a stewardship organization could be established voluntarily, more likely state legislation would be required.

9 Oregon Program and Funding Recommendations

Inadequate disposal options for unwanted and unused medicines can lead to serious problems including:

1. Avoidable poisonings of both children and adults,
2. Intentional misuse of unwanted prescription drugs, especially by teenagers,
3. Water quality degradation from flushing unwanted medicines down the toilet.

An ***Oregon Drug Take Back Program*** could help address each of these problems. The majority of the Stakeholder Group believes that the social benefits of a successful take back program -- decreasing avoidable poisonings and reducing teen access to pharmaceutical drugs -- are the most compelling reasons for instituting an Oregon program.Since the majority of drugs that enter Oregon's waterways are excreted, current science indicates that eliminating unwanted drugs from being flushed down the toilet will have only a small impact on water quality. However, the group believes that a drug take back program is a prudent precautionary step and a component of raising the public's awareness of chemicals in the environment. A successful drug take back program will allow households and long term care facilities to conveniently return unwanted and unused drugs, both over-the-counter and prescription drugs, for safe disposal -- possibly a return bin at a pharmacy or a mail-back system.

After researching the problem and possible solutions to provide for proper safe disposal of unwanted medicines, the majority of the ***Oregon Drug Take Back Stakeholders*** group recommends the establishment of a product stewardship program for safe and environmentally-sound collection and disposal of unwanted medicine. This program would be similar to the successful approach employed by the pharmaceutical industry in British Columbia. In British Columbia, unwanted and unused drugs are returned to one of 844 participating pharmacies in 131 cities. The program has been in place since 1996, and is funded by the Post Consumer Pharmaceutical Stewardship Association, an industry association. The collected drugs are incinerated. In 2005, the program collected 39,710 pounds of unwanted drugs. The annual cost of the BC program in 2005 was $190,935 (US dollars). The group believes that this approach, which has also been used in other industries in the US and Canada, has the best potential for success. If the Oregon program is as successful as the BC program, we would anticipate collecting up to 60,000 pounds of unwanted drugs annually for proper disposal.

A product stewardship program for Oregon should follow other states and communities that are seeking federal Drug Enforcement Administration (DEA) waivers or exceptions to allow drug take back programs to conveniently collect unwanted controlled drugs. Under the Controlled Substance Act regulations administered by DEA, only law enforcement officers can collect unwanted controlled drugs such as Vicodin, Demerol, Ritalin, Xanax[30]. Programs in Washington, California, and Maine have already requested DEA waivers or exemptions to collect unwanted controlled drugs. The Oregon Drug Take Back Stakeholders Group will support waiver requests

[30] See 21 Code of Federal Regulations 1300 - 1316

for similar drug take back programs. Also, the group calls upon the DEA to assist in establishing effective drug take back programs nationally.

The Stakeholder Group was not unanimous in its recommendation – this proposal represents the majority of the participants, but not every member.

The Pharmaceutical Research and Manufacturers of America (PhRMA) does not support the proposal.

9.1 *Proposal*

The majority of the members of the group proposes that the pharmaceutical manufacturers and over-the-counter drug companies be requested to devise and implement a convenient and effective program for consumers to dispose of unwanted medicine. If the industry is unable to move forward with such a program, the group proposes that legislation requiring such a program be introduced in the 2009 Oregon Legislature.

The group believes an appropriate program should accept unused and unwanted medicines including controlled drugs and over-the-counter drugs. It could be a mail-back or convenient drop-box program, or a combination. However, the group believes that there may be other viable program designs that industry may choose to pursue.

The group does not support adding drug take back programs to the routine responsibilities of Oregon's law enforcement agencies.A strong statewide education program will be needed if the drug take back program is going to be successful.

9.2 *Funding*

The group believes that industry should fund the program similar to the funding mechanism used in British Columbia and in the recycling of used batteries and electronic equipment in the US.It does not believe that the burden of this program should fall directly on consumers.

9.3 *Additional Recommendations*

For the key subgroups, additional recommendations include:

- **Hospitals**

  A survey should be conducted to better assess the drug disposal policies and practices of Oregon hospitals, especially rural hospitals with less access to reverse distributor services. Based on the information in the survey, DEQ, local government pretreatment programs, and affected hospitals should agree to a set of Best Management Practices for unwanted drug disposal that all Oregon hospitals can follow.

- **Long Term Care Facilities**

  Oregon DEQ, the Oregon Public Health Division, local municipalities, and long term care providers should agree to a set of Best Management Practices for unwanted drug disposal from long term care facilities and group care homes.

- **Public**

  The group recommends that a product stewardship program as presented above be developed to collect unwanted and unused medicines, including controlled drugs, from the public.

10 Appendices

10.1 Appendix A: Charter

Oregon Pharmaceutical Drug Take Back Program Stakeholder Group

CHARTER

GOAL

Work collaboratively with affected and interested stakeholders to develop a workable Oregon drug return system that collects and properly disposes of unwanted prescription drugs, controlled substances, and over-the-counter drugs from the end users.

PURPOSE

The Oregon Drug Take Back Program Stakeholder Group is a group convened by the Oregon Board of Pharmacy, Oregon Department of Environmental Quality, Oregon Water Utilities Council, and the Oregon Association of Clean Water Agencies.

The Group will meet to reach consensus on the best drug take back program for Oregon in its report.

Proposed Scope of Work

The Stakeholder Group will:

1) Review Stakeholder Group membership and consider if any key stakeholders should be added.
2) Provide background information and research on drug return systems including:
    a) Oregon and US regulatory framework including handling of controlled substances under the US Drug Enforcement Administration regulations, along with Environmental Protection Agency (EPA) and Oregon Department of Environmental Quality environmental regulations;
    b) Experiences of other communities in the US and other locations in instituting drug take back programs;
    c) Needs and desires of all stakeholders, including Oregon pharmacy owners and operators, both independently-owned and chains; and
    d) Possible funding mechanisms for both start up, promotion, and on-going collection and disposal costs.

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3) Work with stakeholders to consider any necessary changes to regulations or statues.

4) Develop stakeholder group consensus on the best drug take back program for Oregon that is effective, includes both controlled and routine drugs, and is as economical as possible. The proposal should outline key education and outreach elements for a successful and effective program.

Advisory Committee members acknowledge that there may be specific topics where they will "agree to disagree", and that dialogue and discussion on controversial topics is valuable.

The Group decided to use a decision making process of "modified consensus minus one".

The project deliverable will be a signed consensus report from the stakeholders outlining the preferred Oregon pharmaceutical drug take back program, including regulatory recommendations and permanent funding methods. Additional recommendations regarding funding for startup costs will also be addressed.

The project will start in the fall of 2006. The stakeholder advisory group process is anticipated to take 9 – 12 months. Six to eight meetings are anticipated over the course of the project. Meetings will likely be held in Salem or Portland.

Stakeholder Group

Members of the Stakeholder Group include:

- Oregon Board of Pharmacy
- Oregon State Pharmacy Association
- Oregon Society of Health-System Pharmacists
- National Association of Chain Drug Stores
- Oregon Hospice Association
- Oregon Public Health Division - Environmental Public Health
- Oregon Environmental Council
- Oregon Poison Control Center
- Oregon Refuse & Recycling Association
- Oregon Association of Clean Water Agencies
- Oregon Water Utilities Council
- Oregon Department of Environmental Quality
- Oregon State Police
- Oregon Association of Chiefs of Police
- Oregon Sheriffs Association
- Tualatin Valley Water District
- Willamette Riverkeeper
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- State Medical Examiner's office/Clackamas County Medical Examiner
- US Drug Enforcement Administration
- Council of Local Public Health Officials
- Northwest Product Stewardship Council
- Covanta Marion Waste-to-Energy facility

Meeting Organization

The meetings will be co-chaired by Tom Penpraze of the City of Corvallis, and Tony Burtt of the Oregon Board of Pharmacy. Janet Gillaspie of the Oregon Association of Clean Water Agencies will provide meeting facilitation and organization assistance. A graduate student at Oregon State University, Monica Hubbard, will provide research and writing services to the stakeholder group at the direction of the co-chairs and facilitator.

The co-chairs will work with the facilitator to generate agendas cooperatively. Committee members will have an opportunity to add items to the agenda. Occasionally, outside speakers with a particular expertise may be asked to address the Stakeholder Group. Time will be set aside at each meeting to hear from interested members of the public - - although this time may be limited to ensure the Stakeholder Group can accomplish its mission in an efficient manner.

Each participating organization is responsible for appointing a qualified individual to participate in the Stakeholder Group. Both a primary contact and an alternate will be allowed to participate in the group. The primary contact and alternate agree to provide each other information to ensure both are prepared to fully participate in the Committee's discussions and recommendation development.

A general summary of each meeting will be prepared.

10.2 Appendix B: Stakeholder Meeting Summaries

10.2.1 MEETING 1: NOVEMBER 9, 2006

Oregon Drug Take Back Stakeholder Meeting

9 Nov 06

SALEM, OREGON

Attendance at end

INTRODUCTIONS

The group introduced themselves.

Janet Gillaspie of ACWA set a few ground rules for the group, including:

- Stay with Group
- No side conversations
- Cell phones off or to stun
- No Blackberries
- Learn from others
- Contribute ideas

Purpose of Stakeholder Group

Co-Chair Tom Penpraze outlined his views about the need for the stakeholder group. He indicated that from a drinking water and wastewater utility point of view, drugs being flushed down the drain are a problem. Municipal drinking water treatment plants are not designed or operated to remove drugs, and wastewater treatment systems are not designed to remove drugs from the treatment systems.

Penpraze advocated that pollution prevention is the best way to address concerns about possible contaminants reaching waterways -- keep unused drugs from reaching the landfill by being discarded in the trash or the wastewater treatment system by being flushed down the toilet.

He continued that an effective drug take back program will benefit Oregonians -- not just for water quality reasons, but also addressing concerns related to drug abuse prevention and reducing accidental poisonings.

Penpraze indicated that the drug take back program should meet goals of public health protection, impacts on water supply, environmental protection, and impacts on fish and wildlife, such as impacts on fish antibiotic resistant bacteria. There are many good reasons to build an effective drug take back program for the state.

Co-Chair Tony Burtt continued that people come at this issue from two perspectives – and both are around the table in the meeting. There are the water supply and wastewater contamination issues with chemical traces in surface and ground water.

The other is the harm that controlled substances on have young people and others - - how do we get the unwanted controlled substances out of the system to stop addiction. The misuse of illegal prescription drugs is the fastest growing area of drug abuse, he said. The issue of drug abuse is what is driving the public issues. The environmental issues are important, but the drug abuse is the "headline grabber".

Burtt continued by explaining that he is on the staff of the Board of Pharmacy. The Board of Pharmacy is a 7-member citizens commission appointed by the Governor and confirmed by the Senate. The Board's authority ends when the drug is prescribed or delivered to the patient. This program is focused after that step, observed Burtt.

He continued that the Board of Pharmacy strongly supports the effort of this group, and has passed a rule to facilitate a rule to take back noncontrolled substances (unwanted, noncontrolled). The obstacle is the return of controlled drugs, and the DEA regulations. The challenge is to create a program that can deal with the polluting substances, but is not butting against the wall of the DEA regulations.

We can facilitate getting noncontrolled drugs out of environment; the challenge will be to recognize what we can achieve.

Purpose of group

The group added some thoughts about the drug take back program before it started tackling its charter. Items mentioned included:

- Lisbeth asked what drugs can be returned – Burtt indicated that there are pharmacies that can return noncontrolled drugs. Issues include: work load, disposal options, and company policy.
- Gerry added that there are two goals – cleaning up the water and to get the drugs out of the cupboard.
- Currently, there is a reverse wholesaler for returning drugs from the pharmacy or drug store – drugs that have not been prescribed. The nearest reverse wholesaler is CA.
- What is the preferred disposal method for collected drugs – likely incineration.
- Boudouris indicated that DEQ had recommended that drugs be flushed down the toilet, but does not recommend that anymore. They currently recommend disposal as solid waste. Now there are more concerns about long-term care facilities - - this is a 'Catch 22' for DEQ.
- Jim Thompson indicated that the reverse wholesaler system is likely to be a solution - - it is intended for large amounts of untouched, known drugs.

Charter Issues

The group worked through the draft charter. Under **Goal**, it agreed to these changes:

- Target substances are prescription drugs, controlled substances, and over-the-counter drugs. This includes veterinary medicines.
- Broaden scope beyond "consumers" to "end users" – this would include long-term care facilities and other institutional settings.

Under **Scope of work**, Burtt indicated that there is no need for rulemaking at this time. The paragraph was removed.

There was discussion about the funding element of the program - -the will of the group was to retain the phrase.

There was discussion about what was "consensus". Consensus is 100% "can live with it" said Gillaspie. After discussion, the group asked that the February meeting include a presentation on various consensus models that might be used.

Revise statement to read: ***"Work with stakeholders to consider any necessary changes to regulations or statues."***

The group had additional suggestions for adding groups to the **Stakeholder inventory** – addressed later in the meeting summary.

The group noticed that the scope of work element was repeated in the draft and that should be corrected.

A copy of the revised charter is attached.

Stakeholder Inventory

The group suggested additional stakeholders for the process. Those suggestions included:

- Oregon Health Care Association (long term care providers)
- American Red Cross
- Oregon Fish & Wildlife Department/US Fish and Wildlife Agency
- US Geological Survey
- Department of Human Services – Division of Aging (SDSD)
- Generic Pharmaceutical Association
- Consumer Health Products Association
- Oregon Retail Council
- Oregon Medical Association
- Oregon Nurses Association
- Oregon Association of Hospital and Health plans
- Oregon Grocery Association

The stakeholder group members that suggested these groups will forward contact information to Gillaspie.

The people that made these suggestions will e-mail Gillaspie the contact information for the group that they suggested.

Meeting Outline

The group reviewed the draft meeting schedule.

The group made these suggestions:

- February – add consensus decision making model; add infrastructure inventory; add update from the programs listed plus the City of Newberg pilot project
- March – add legislative strategy assessment

Etter suggested that a second DEA-type conference might also be a good step to add.

Scheduling

The group discussed scheduling its meetings. Miller highlighted that for the lobby types that will be participating, scheduling any meetings Monday through Thursday is very difficult. Friday meetings would be best. The group used a chart to indicate their meeting preference.Gillaspie will review the chart and distribute a draft meeting date to the group and hopefully schedule the rest of the meetings.

The Willow Lake Treatment plant is likely a good spot for the meetings.

Report Table of Contents Review

The group added - 'obstacles & constraints' under "program elements, and 'regulatory and legislative recommendations'

Meeting Check Out

The group considered the elements of the meeting that needed improvement, and those elements that worked well.

The meeting needed more coffee and more background information on the problem would have been useful.

The elements of the meeting that worked well included:

- Organization of the meeting
- Meeting space
- Planning that went into preparing for the meeting
- Having a draft charter to work from
- Posting information and studies on the ACWA web site

Other Items

Etter indicated that there is a list serve for those interested in tracking this issue nationally. Contact Etter to be placed on the list serve,

Gillaspie highlighted a series of reports loaded on the ACWA web site related to drug take back programs. She asked stakeholders that have reports and information to share to forward it to her for posting on the site.

Overall the group was interested in additional background information about the extent and characterization of the problems related to unwanted drugs from a water quality, accidental poisoning, and illegal prescription drug abuse perspective.

Gillaspie indicated that that information would also be presented in the workshop scheduled for 11/13/06, and the presentations from the workshop would be posted on the ACWA web site.

Items to learn about

The group started a list of items they wanted to learn more about – this included:

- Reverse wholesale distribution system
- Preferred method of disposal in Oregon for collected drugs

Stakeholders Attending:

- Tom Penpraze, City of Corvallis (Oregon Water Utilities Council)
- Tony Burtt, Oregon Board of Pharmacy
- Gerry Migaki, Oregon Society of Health-System Pharmacists
- Jim Solvent, Council of Local Health Officials/Council of Environmental Health Supervisors
- Therese Huntsinger, Oregon Environmental Council
- Brenda Bateman, Tualatin Valley Water District (Oregon Water Utilities Council)
- Kristan Mitchell, Oregon Refuse & Recycling Association
- Shawn Miller, National Association of Chain Drug Stores
- Bill Etter, Drug Enforcement Administration
- Tonya Drayden, Oregon Poison Center
- Lt. Mike Dingeman, Oregon State Police
- Jim Gardner, PhRMA
- Abby Boudouris, Oregon DEQ
- Jim Thompson, Oregon State Pharmacy Association
- Ann Jackson, Oregon Hospice Association

Others Attending:

- Jeff Bickford, Marion County Solid Waste
- Sharon Olson, City of Eugene
- Nancy Toth, Eugene Water and Electric Board
- Lizbeth Ward-Fowler, Oregon Poison Control (alternate)
- Marney Jett, Clean Water Services
- Brett Hulstrom, City of Portland
- Lacey Bettis, Oregon State Police (alternate)
- Holly Sears, Oregon Refuse & Recycling (alternate)

Janet Gillaspie of ACWA facilitated the meeting.

10.2.2 MEETING 2: FEBRUARY 9, 2007

Oregon Pharmaceutical Drug Take Back Stakeholder Meeting

09 February 2007

Salem, Oregon

MEETING SUMMARY

INTRODUCTIONS

The participants introduced themselves. Janet Gillaspie, ACWA, pointed out the copies of the group's charter available around the table and directed the attendees to review the highlights from the last meeting.

Support for Drug Take Back Program

The meeting participants went around the table and each described the reasons their group supports a drug take back program. The reasons included:

- The responsible way to tackle the problem is to educate the public. Drug take back should be the public's responsibility with all stakeholders participating. This is not an environmental problem. Awareness campaign focused on drug control and safety issues is what is needed. Support proper disposal.
- Good stewardship program – concerned about improper prescription drug abuse
- Remove some pharmaceuticals from public water supplies (repeated)
- Public perception of drinking water quality and ecological concerns
- Wastewater treatment plant concerns; need to inform the public of the proper and safe disposal method (repeated)
- Need a unified message on the proper and safe disposal method
- From a public health point-of-view, support drug take back from a safety issue in both homes and care settings
- Safe disposal of unwanted medication
- Easy-to-use program to get drugs out of sewers; help wastewater treatment agencies meet discharge standards (repeated)
- Reduce pharmaceutical wastewater into waterways – potential human health and wildlife issue – need to be able to tell people the right way to dispose of unwanted medicines
- Appropriate and legal disposal of unwanted drugs
- Safe, secure and on-going program to make drug return as safe and convenient as drug buying
- Part of having a safe and healthy community. Need to avoid garbage disposal – household hazardous waste collection stations are not the right vehicle for drug disposal. Water quality concerns, including Tribal Nation concerns for salmon

- Groundwater, surface water, and drinking water concerns – want to keep drugs out of garbage also. Need tools for public to have safe return system. Should be using the pre-cautionary principle for tackling this issue now.

Concerns about Drug Take Back Program

The group also expressed their concerns about a drug take back program. These included:

- Focus on public safety message – this is a poison control issue, not a problem in water. The microcontaminants found in water are over-the-counter products like insect spray (DEET) and beauty products. Education is the key
- Not an unfair workload or cost on pharmacists or other regulated entities
- Program must meet legal requirements
- Funding must be fair, acceptable, and equitable
- Safety of program staff as drugs are consolidated
- Impact of drug incineration on air quality
- Ease of use – the program needs to be very easy to use; needs long term funding base
- Roles, scope and responsibilities of everyone involved must be very clear. Who will fund the program? Who is in charge of the program? What are the roles of others involved?
- Education is very important – this is more a poison control issue than a water quality issue
- Program must be legal, simple, useable, and cheap
- Keep in mind that tracking the programs success using water quality indicators is not likely to be possible
- Drug take back program only addresses a small part of the overall problem of pharmaceuticals in water quality. Need to review the air quality impacts of increased incineration
- Oregon State Police has concerns about being the only law enforcement agency collecting drugs. OSP concerns include volume, costs, and proper disposal. All Oregon law enforcement agencies should be involved in collecting drugs. Getting firm numbers about the amount of drug diversion that is coming from the medicine chest - - rather than from false or frequent prescriptions, over the Internet or from other countries - - will be difficult.
- Design the program you want first; tackle how to fit that in the regulations later
- Anticipate a pent-up demand from the public for proper disposal when it is available; the public demand may drive the program
- Public concerns may flood a drug take back program; important to tackle who pays – not appropriate for government to pay these costs. The costs should be shared across all players. Program should work as well in rural Oregon as it does in urban Oregon.

Jack Geisser of PhRMA suggested that the Generic Manufacturers' Association and the Consumer Products Council be invited to the meetings as they are stakeholders. Gillaspie asked him to provide contact information.

Tom Penpraze of the City of Corvallis asked if there was a uniform definition of "pharmaceutical." Gillaspie pointed out that the definition had been agreed upon and was part of the group's charter.

Gerry Migaki of the Oregon Society of Health System Pharmacists (OSHP) stated that basing success on water quality issues alone was not the best strategy. Poison control and prevention of drug abuse are also important factors. This opinion was seconded by Jim Hill of the City of Medford and David Stitzhal of the Northwest Product Stewardship Council.

PH:ARM

Stitzhal and Sego Jackson of the Snohomish County Solid Waste Management Division presented information on the pilot drug take back program in the Puget Sound area, PH:ARM. Stitzhal stated that the project consisted of 7 collection sites in Kaiser Group Health locations. In 8 weeks, 55 buckets at one gallon each of returned drugs were collected. In the future, collection sites at Bartell's Drugs locations are planned. Controlled substances were not allowed in the collection buckets.

A survey of the buckets showed that they contained almost all pharmaceuticals. There was some garbage in the buckets, but not much. The project is trying to change the federal law on controlled substances. They have petitioned the U.S. Department of Drug Enforcement Administration for a waiver and hope to mimic the success of the British Columbia program.

Jackson said that they provided specially designed plastic buckets and metal boxes for the collection sites. They are moving toward a design of a wheeled tote system. The initial take back program was to have been a quiet launch, but the information was published in a Group Health newsletter and interest was greater than anticipated. He recommended a tight communication plan and a designated team to control information for future take back projects. Funding was provided by government funds as well as support from Kaiser Group Health. There is tremendous pent-up demand for disposal sites from the public, he added.

Tony Burtt, Oregon Board of Pharmacy, asked about supervision of the drug return box and concerns about the potential mixture of incompatible substances. Jackson was unsure whether there was any direct supervision of the drug receptacles, but the boxes were in the clinics in plain sight. The size of the drug container deposited by the consumer is limited due to the size of the opening.

Hill brought up concerns with security of the boxes and also with Health Information Privacy Act (HIPAA) rules. Jackson said that the boxes do not increase security concerns. The warehouse that holds the full buckets is a secure facility.

Program Cost Options

Monica Hubbard of Oregon State University presented a PowerPoint program on her research of the cost estimates for funding different types of drug take back programs. A copy of the presentation is posted on the ACWA website at www.oracwa.org. Gillaspie distributed a feedback chart for participants to complete. Stakeholders are to review the details of each drug take back program option and provide their detailed comments to the ACWA office by 1 March 07.

Geisser expressed concerns about mailing drugs. The packages/envelopes would be identifiable and would be easy for drug abusers to take.

Burtt stated that since insurance companies allow insurers to obtain up to 90 days of medications at a time that there will be larger amounts of drugs in the pipeline. He speculated that there will be more drugs received by a take back program in Oregon than the one in British Columbia.

Gillaspie will send the feedback form to the stakeholders electronically. Rebecca David, Oregon State Police, pointed out that there are shipping regulations that may be needed to be reviewed if drugs are to be mailed or shipped. Hubbard will follow up with David to inventory U.S. Department of Transportation regulations that might affect the program.

Jackson suggested that Hubbard look at potential changes in regulations that might be needed. He also suggested getting additional information such as what treatment costs would be for hospitalization of a poisoned child or rehabilitation of a drug-addicted individual. This would allow for better perspective of the costs of the take back program versus the costs of not having a program.

The group discussed several other ideas for take back programs:

- Mailing unwanted drugs directly to a licensed hazardous waste incinerator
- Mailing unwanted drugs to the DEA

The feedback forms regarding program costs are to be returned to the ACWA office (fax at 503-236-6719 or e-mail at *Gillaspie@oracwa.org* by March 1, 2007.

Pharmaceutical Take Back Programs in Adult Care Facilities

Dr. Brenda Bateman, Tualatin Valley Water District, presented a PowerPoint presentation called ***Pharmaceutical Take Back Programs in Adult Care Facilities***; an overview of a program in Newberg, OR. A copy of the presentation is posted on the ACWA web site at *www.oracwa.org*.

There was discussion regarding the inventory process in collecting and documenting the take back of pharmaceuticals. Different law enforcement jurisdictions may need an additional or different inventory process than that established in Newberg. Protocols need to be established that will prevent the diversion of drugs. Migaki asked if consent was needed to destroy prescriptions held in an adult care facility; the group thought consent had likely already been provided.

Decision Making Model

Gillaspie stated that the stakeholders needed to decide on which decision-making model would be best for the group. A handout describing different decision making models was distributed.Burtt presented an additional model, the ***consensus minus one model.*** This model is where an agreement can be made with one dissenting vote noted. Hill stated that he had been in groups in the past that had used this model. Geisser disagreed with the adoption of this model, especially if funding issues are being decided and said that if complete consensus could not be achieved, then an issue should be left out of the proposal.

Teresa Huntsinger, Oregon Environmental Council, felt the modified consensus model would work best. Stitzhal suggested that the outcome defines the model; if the outcome is to be a report with recommendations then a modified consensus model would be most effective.

To decide this issue, the group moved to voting. The vote was a follows:

- The vote for the ***total consensus*** model was 1.
- Penpraze suggested a ***modified consensus model with a final vote*** option.
- The vote for a ***modified consensus*** model was 5.
- The vote for a ***modified consensus minus one*** was 9.

The model adopted is the modified consensus minus one. Gillaspie will revise the group charter to reflect this.

Small Groups

Gillaspie stated that small groups of stakeholders will tackle drug take back program issues, such as the preferred program type and funding issues, for three separate drug user groups:

1. Public group - Chair, Tonya Drayden-Oregon Poison Control Center
2. Adult care group - Chair, Brenda Bateman, Tualatin Valley Water District
3. Hospital group - Chair, Kevin Masterson, Oregon DEQ

Each meeting participant was invited to select the group that they wished to participate in. Small group recommendations will be presented at the April meeting.

The next meeting will be held March 9, 2007

Attending the meeting were:

- Jack Geisser (by phone)-PhRMA
- Rebecca David-Oregon State Police
- Monica Hubbard-Oregon State University
- Sego Jackson- Northwest Product Stewardship Council / Snohomish County Solid Waste Management Division
- David Stitzhal-Northwest Product Stewardship Council
- Mike Dingeman –Oregon State Police
- Teresa Huntsinger-Oregon Environmental Council
- Dave Leland-Department of Human Services – Drinking Water Program
- Tom Penpraze-City of Corvallis
- Tony Burtt-Board of Pharmacy
- Abby Boudouris-DEQ
- Jane Thompson-City of Springfield
- Sharon Olson-City of Eugene
- Jim Hill-City of Medford/ACWA
- Gerry Migaki-Oregon Society of Health System Pharmacists
- Brenda Bateman-Tualatin Valley Water District
- Marney Jett-Clean Water Services
- Janet Gillaspie-ACWA

Notes taken by LD Michaelis. 2/9/07

10.2.3 MEETING 3: MARCH 9, 2007

Oregon Pharmaceutical Drug Take Back Stakeholder Meeting
09 March 07
Salem, Oregon
MEETING SUMMARY

March 9, 2007 Oregon Drug Take Back Stakeholder Meeting Summary

INTRODUCTIONS

Tom Penpraze chaired the meeting. Janet Gillaspie asked if there were any changes to be made to the agenda; no changes were requested. The meeting participants introduced themselves.

Oregon Pharmaceutical Drug Funding Options

Monica Hubbard presented her revised research on program costs. The proposals include increased labor costs as well as an 150% increase of pharmaceutical waste amounts (increase over BC model since US drugs are often dispensed a month at a time).Hubbard reviewed the previously outlined options for the Drug Take Back Program:

1. Installed – no mailer
2. Installed with mailer
3. All pharmaceuticals returned at local law enforcement
4. Oregon State Police mailer
5. Reverse distributor mailer

Rebecca David emphasized that there is a stigma associated with visiting a police station. Abby Boudouris asked if it was assumed that there would be one pill bottle per mailer. She stated that larger drug amounts would be returned from hospice and care facilities. Hubbard stated that the mailers would be designed to hold up to one half pound of drugs. Jim Hill asked if there would be an ability for a consumer to use a different type of box or shipping method, other than the mailer, to send in the pharmaceuticals. Hubbard agreed that the consumer could use a different method, if they wished. Marney Jett questioned if the mailers would be available from clinics and pharmacies. Hubbard said yes, but it is still unclear how they will be distributed.

Jack Geisser questioned if all the drugs received back could be assumed to be controlled substances, thus removing the need to sort the materials when received. Bill Etter stated that in order for pharmacies to receive controlled substances there would need to be a police presence on site or they would have to receive an exemption from the Drug Enforcement Administration (DEA).

Jim Hill said that the hospitals in Southern Oregon use reverse distributors for unwanted drugs. Reverse distributors do not count the drugs – they assume that they are disposing of controlled substances. Etter stated that the DEA exemption requested by the reverse distributor EXP of California would allow them to receive drugs from a non-registered user.

Brenda Bateman said that in the option where the drugs were to be returned to law enforcement offices, the drugs will need to be sorted as there are a handful of types that are not accepted at the incinerator in Brooks. Boudouris asked if another option to consider would be one where consumers mailed pharmaceuticals to hospitals since the hospitals use reverse distributors. This would be particularly useful for people living in rural areas or small towns. Brett Hulstrom questioned if liquids would be received for disposal. Hubbard stated that liquids had not been considered in the mix. Sego Jackson said that the pilot project in Puget Sound only considered disposal facilities that were licensed hazardous waste management facilities.

Gillaspie asked the group if they felt this was the best review of options; if the proposals were on the right track.

Geisser stated that he felt the law enforcement costs estimated were too high. Gerry Migaki asked if reverse distributor mailer (option 5) was used and a consumer had a lot of pharmaceuticals to return, could they use multiple prepaid mailers. Hubbard said that they could use as many as needed

Jackson questioned if costs would increase if the program used a hazardous waste incinerator facility. Hubbard said that options 2, 3, and 4 anticipate use of a licensed hazardous waste incinerator.

Hill emphasized that a contract for disposal through a reverse distributor should be placed out for bid, so that more than one vendor can offer a proposal. Each reverse distributor would need clearance from the DEA. Boudouris stated that facilities considered should be located only in the US. Those located outside the US are problematic.

The group had no other program options to suggest and no further changes to the cost estimates for the drug take back program.

Drug Take Back Program funding options

Hubbard presented her research on funding options. The options are:

1. Waste Disposal fees
2. Pharmaceutical fees
3. Mix of 1 & 2
4. State General fund
5. Water Utility charge

Geisser emphasized that that the program needs to be considered a social issue, not an environmental one. He also objected to option 2, pharmaceutical fees. Fees need to be equitably distributed. By levying fees only on pharmaceuticals, not all of the stakeholders are shouldering their share of the costs, he stated.

Hill questioned if the funding options were for a pilot program or for an ongoing one. Hubbard stated they were for an ongoing program. Migaki asked if there was anticipation for a larger amount of disposed drugs in the first year of the program; Hubbard said no.

Gillaspie asked for comments from the group regarding the funding options outlined.

The comments included:

- A mix of funding options makes for more work and less stable funding. The reverse distributor option is the best.
- We are asking the wrong people to pay if this is to be an ongoing program.
- Mixing funding options is a good idea as the responsibility is then spread around; each area is impacted by drug disposal. A pharmaceutical fee as the only funding source is not a feasible approach.
- Do not ask participants to pay when they turn in the drugs. It will be difficult to collect fees from the different water agencies if a water utility charge is assessed. Solid waste fees may be simpler. Consider adding both commercial and industrial wastes to the solid waste fees to broaden the base paying the fee.
- Legislative appropriation is best for administering a statewide program but difficult to get.
- There should be an emphasis on product stewardship. There should also be consideration if this is the right use of solid waste tipping fees - - the solid waste industry group may have concerns about the fees. Consider who is impacted and who benefits and put a fee system in place based on the beneficiaries. Need to weigh the solid waste fee against the other solid waste funding needs.
- Difficult to institute a wastewater or drinking water utility fee; try to make the system as simple as possible.
- Pharmaceutical fees are best – those who use the drugs pay for the disposal of the drugs.
- Any funding option that works is acceptable.
- The pharmaceutical industry representative suggested that the State General Fund would be the best funding solution. If not that, then funding responsibility should be shared equitably by everyone affected, including the consumer health product industry, not just the pharmaceutical industry.Some large stakeholders, such as the consumer health products industry, are not represented in our forum.
- Utility billing is difficult and state general fund dollars are not possible. Adding more items to the solid waste tipping fee is not a good idea. Use a product stewardship model for developing the funding proposal. That helps get valuable information about medications that are not being used into the 'loop'. Need to ensure that generic and over-the-counter drugs are included also.
- Spreading the costs to the greatest number of people would be best as the results are for the greater good.

Other Ways to Fund a Program

Gillaspie asked participants to continue with comments on other ways to fund a drug take back program. The comments included:

- The best option would be to get voluntary funding from all groups. Expecting a legislative fix would be an uphill battle.
- We need to look at this problem "cradle to grave". Create an incentive by getting the pharmaceutical manufacturers to pay. State General Funds not likely.
- A taxing model based on consumption would be the fairest.
- See who benefits – it is kids, fish, and wildlife. Use a product stewardship model and craft a program that can work nationally - - not just in Oregon.

- Pharmaceutical fees or solid waste fees would be the best and most usable solution.
- Explore a product stewardship model, like the auto mercury switch group – more information is available at http://www.elvsolutions.org/about.htm
- There are many good options; not sure which is best.
- Industry should contribute. Look at the existing model of the mercury auto switch program as a template.
- Sharing fees would be the most likely source of funding.
- Everyone benefits from improved water quality, not just the consumers.
- A small tax should be levied on each prescription.
- While legislative change might be difficult, it is still possible with enough supporters involved.
- Taxes on prescriptions would raise prices.
- We need to mimic the British Columbia model where industry trade groups provide funding.
- A $.026 tax on each prescription in Oregon would raise $800,000 for this program.

Small Group Work

The three small groups – Hospital, Public, and Adult Care met to discuss their topics. The respective group chairs reported on the progress of their groups.

Hospital – Kevin Masterson, DEQ: Approximately 90% of hospitals are covered by existing systems. The group will follow through with the Oregon Hospital Association (OHA) to see what smaller hospitals are doing to dispose of unwanted drugs. The group will also determine what method is used to dispose of chemotherapy drugs.

Public – Tonya Drayden, Oregon Poison Center: The ideal system would include drop boxes and mailers. The ability to use drop boxes for controlled substances would be necessary and reverse distributors would be used to collect the drop boxes. Etter stated that the reverse distributor would need to be allowed by the DEA to handle the boxes without law enforcement responsibility. Also, need to have an education program in place to inform the public. This would include public service announcements and visits to community groups by the Oregon Poison Center.

Adult Care – Brenda Bateman, Tualatin Valley Water: Staff of the facilities will be unable to take drugs from the facility to a disposal site. Law Enforcement staff would likely be needed to collect the drugs. A reverse distributor that has a custodial exemption from the DEA would be a useful option. Adult foster homes and hospice would participate more as a household entity. Hospice is a different issue as they are dealing with hazardous substances and controlled drugs.

Hill asked if this group could offer support to ensure that EXP receives the DEA exemption it has requested. A letter to DEA will be drafted under Tony Burtt and Tom Penpraze signatures supporting the exemption.

Gillaspie proposed visiting Ann Jackson at the Oregon Hospice Association to talk about Drug Take Back issues.

Drayden will contact the California Poison Control system to get their support for EXP's DEA exemption request.

The next meeting is scheduled for April 13, 2007, 9:30am to Noon at Willow Lake Treatment Plant in Salem.

Other Issues

The group recorded these issues to be further explored:

- Consider how the mailer will handle larger quantities such as from hospice or long term care facilities?
    - Maybe just have the mailer large enough to hold about ½ pound and instruct people not to 'overstuff' it, but to get more mailers
- Some provision for "cradle-to-grave" responsibility should be added to any waste disposal contract; ensure that the returned materials are being properly disposed of and not shipped out of the US
- Add the information on the USDOT regulations
- How to handle liquids?
    - Group thought that these might not be able to be handled in the program
- There are specific types of only six pharmaceuticals that are not acceptable at Brooks incinerator – track this
- Maybe the return program should be just to the hospital pharmacies (some thought no)

Meeting 'to do'

- Add information on US DOT regulations to report to ensure allowable thresholds for mailing are not exceeded
- All participants will review the list of possible grant agencies for start up funding and add their additional ideas; submit to ACWA office by 3/23/07
- Explore product stewardship models, such as the auto mercury switch group example
- Write a letter of support to the appropriate person regarding the DEA exemption for the EXP reverse distributor in California
- Get the consumer products and over–the-counter groups involved

Attending the meeting was:

- Jack Geisser (by phone)-PhRMA
- Rebecca David-Oregon State Police
- Monica Hubbard-Oregon State University
- Sego Jackson- Northwest Product Stewardship Council / Snohomish County Solid Waste Management Division (by phone)
- Bill Etter-DEA
- Kevin Masterson-DEQ
- Dave Leland-Department of Human Services – Drinking Water Program
- Tom Penpraze-City of Corvallis
- Tonya Drayden-Oregon Poison Center
- Abby Boudouris-DEQ

- Jane Thompson-City of Springfield
- Karen DeBaker-Clean Water Services
- Jim Hill-City of Medford/ACWA
- Gerry Migaki-Oregon Society of Health System Pharmacists
- Brenda Bateman-Tualatin Valley Water District
- Marney Jett-Clean Water Services
- Brett Hulstrom-City of Portland BES
- Janet Gillaspie-ACWA

Notes taken by LD Michaelis, 3/09/07

10.2.4 MEETING 4: APRIL 13, 2007

Oregon Pharmaceutical Drug Take Back Stakeholder Meeting

13 April 2007

Salem, Oregon

MEETING SUMMARY

INTRODUCTIONS

Tom Penpraze and Tony Burtt co-chaired the meeting. Janet Gillaspie asked if there were any changes to be made to the agenda; no changes were requested. The meeting participants introduced themselves.

There are two more meetings of this stakeholder group scheduled for May 11th and June 8th. The group needs to determine what happens after the last meeting.

The sub-committees formed at the last session presented their findings regarding the three take back groups:

- Adult Care Facilities
- Hospitals
- Public

Adult Care Facilities

Brenda Bateman presented the information for the Long Term Care Facilities group. She stated that there are three types of long term care facilities:

- Residential Care
- Assisted Living
- Nursing Homes

The group recommended that the preferred model for a drug take back program for this group is one where an entity, such as law enforcement or a reverse distributor, came to the facility to collect the unwanted medicines. After discussion, the group wanted additional information about the use of reverse distributors for the larger residential care, assisted living, and nursing homes. Perhaps, these facilities will operate more similar to hospitals, and the smaller residential care facilities would operate more similar to a public program.

In the state of Oregon there are approximately 600 facilities with the capacity to care for over 35,000 individuals. All of these facilities are licensed by the state and disposal of drugs is handled by nursing staff with the pharmaceuticals being sorted into controlled and noncontrolled bins. They typically flush the noncontrolled drugs. Some of the facilities with a direct relationship with a pharmacy have the ability to send back unopened, noncontrolled drugs to the pharmacy for reuse.

There are established protocols for disposal of drugs, controlled and noncontrolled, at each facility. A mail back program would be difficult to administer at this level given the volume of the unused drugs. The preferred model for a take back program would be one where an entity, law enforcement or a reverse distributor, came to the facility to collect the discarded medicines.

Education and outreach would be easier to implement with this group since they are generally licensed by the State of Oregon. Bateman agreed that the preferred option for the long-term care facilities is probably not the best one for the public.

A reverse distributor would need an exemption from DEA to be able to go directly to a care facility to collect drugs for disposal.

Tony Burtt stated that once drugs are out of the hands of the professional staff, the drugs cannot be returned to the pharmacy. There would be less professional, medical care at the home hospice and foster home level. Hill supposed that the more involved professional care would be provided by the more expensive centers.

Penpraze asked if there are impediments to a take back program being implemented through reverse distribution in a facility. Gerry Migaki stated that there can be costs to have the drugs taken back by a pharmacy, but in other cases there could be offset credits given.

Gillaspie asked about the cost of establishing programs in facilities. The Portland Police Bureau does not likely have the resources to tackle a drug collection system for long-term care facilities in Portland.

Jim Thompson stated that the variation in sizes of facilities - adult foster homes versus large, institutional care centers – could be a problem. Mom and pop facilities will be harder to monitor. Becky David said that smaller group homes would likely fall under the public/ residential guidelines. Bateman agreed that the preferred system for long-term care facilities would be best for the larger centers.

Burtt said that the larger the institution the more likely there will be a protocol in place to send back drugs. Many of the larger facilities may already have a relationship with a reverse distributor. Education about the availability of reverse distributors should be implemented. In the Newberg take back program, Bateman said that the facilities involved purchased lock boxes with their own funds. There was concern that there might be funding concerns at the lower level facilities.

Jim Hill asked if perhaps having an established drug take back system could be required by the accreditation process. Gillaspie agreed that Oregon Health Services could establish this requirement. If this is a requirement, then pharmacy policies should be in alignment.

There was a recommendation that ***Health Care Without Harm*** be invited to participate in this endeavor.

Hospitals

Kevin Masterson presented the findings for the Hospital Sub-committee. The sub-committee will be doing a survey involving a larger number of hospitals, in the near future. The group will be asking the Oregon Hospital Association for help with distribution of the survey.

All larger hospitals currently use reverse distributors and/or hazardous waste contractors. There may be gaps in drug disposal at the smaller community hospitals, as well as gaps in education and training. There are 300-400 hospitals around the state. It appears that there may be gaps in practices to correct but there is no need to establish a separate hospital-focused drug take back program from the ground up. A mentorship program, with larger hospitals mentoring smaller hospitals or smaller hospitals pooling their knowledge and resources may be workable options.

Hill stated there are concerns with liquid drugs and infrequent incidents when drug dispensing is interrupted by an event. Penpraze emphasized that these situations are exceptions. There was a discussion regarding hospital accreditation policies and procedures.

Kristan Mitchell discussed the difference between capture of hazardous vs. medical wastes. There were questions regarding the licensing and procedures of the growing number of surgi-centers. What group would they belong in? Migaki stated that these centers are licensed and run by physician groups. Migaki, Hill and Masterson will draft a survey to present to the hospitals. They will see if they can get the Oregon Hospital Association to assist them. Masterson will lead the effort.

Public

Tonya Drayden was not available to present the public group recommendations. Gillaspie polled the group and asked them to provide their ideas for the best public drug take back system. The responses included:

- Make it as easy as possible for consumers to use. The mailer option would be easiest to use.
- There are issues with a mailer – who should the drugs be mailed to. We need to first determine a system as to who receives the returned drugs. Patients don't know what a controlled drug is versus a noncontrolled drug. Need to establish a program where this is not a concern. Also, consider mailing the drugs to the DEA
- The program must be simple to use. Expecting consumers to deliver drugs to a law enforcement office is unrealistic. The mail back program appears to be best.
- Skeptical of a mail back program; it may put postal workers at risk. Drop boxes owned and administered by a private company would work best.
- Placing drugs in the garbage is a sensible solution; mailing will be too expensive. The public is only concerned about the costs to them. Review the priorities; is this truly a major concern?
- A drop box system is best. In rural areas, mailers would be needed – and might be teamed with a collection event
- Mail drugs directly to a reverse distributor, if DEA exemption can be obtained.
- Drop boxes will create more work for law enforcement. If drugs are returned to police offices, each item may be need to be checked in and accounted for. OSP stressed that their internal procedures and controls must be followed
- Drop boxes at pharmacies serviced by a reverse distributor would be the best solution. A mail back system should also be established as an alternative option and all drugs should be handled as controlled to avoid the sorting issue. Consider the priorities, not every pill can be accounted for. Garbage may be the correct disposal method for some materials.
- Pharmacists would likely be agreeable to distribute envelopes, but they will not agree to a drug take back system that would require them to devote time to counting drugs. Pharmacies do not have room for a 20-gallon container; their storage facilities are limited. To buy in, pharmacists must be involved a minimal amount of time and have no additional costs levied on them. A mailer makes the most sense as well as handling all drugs as controlled substances.

- A drop box with the DEA waiver for a reverse distributor is best. Providing mailers to rural areas would be too expensive.
- Law enforcement should not be involved. The DEA exemption for reverse distributors is necessary. Drop boxes would be most efficient.

The DEA exemption is necessary. With the exemption, drop boxes at pharmacies would be the best program. Set up pilot collection events to determine public interest and provide education.

Drop boxes at pharmacies similar to the BC system would be best – maybe add a mail back system.

The system needs to be simple. There should be mailers and drop boxes. Make this program as easy as 'Netflix'

Gillaspie asked for three volunteers to work with Burtt and Penpraze to establish a "go" hierarchy. Hill, Boudouris, and Sharon Olson volunteered.

Thompson suggested that there needs to be a centralized warehouse to receive the returned pharmaceuticals. How will that be done? The group is putting too much emphasis on the potential of using a reverse distributor.

Lis Houchen asked how the program would be funded. That is an important question that has not been answered yet.

Draft Report

Gillaspie asked if there were any suggestions regarding what needed to be added to the draft report. Suggestions included:

- Costs of not having a drug take back program
- Break down the funding options between generic and other prescription drugs
- Costs of having a centralized receiving warehouse
- Need more details on contribution of small groups
- Case studies of drug take back programs, such as the City of Vacaville

Gillaspie asked that comments on the report be e-mailed to her.

White House Drug Take Back recommendations

Group members discussed the White House recommendations. There were questions as to why certain drugs were emphasized and others ignored. Why were some drugs supposed to be flushed? One item on the White House list stated that consumers should follow the prescription label that lists the drug should be disposed of by flushing; no one has seen such a label.Boudouris felt that the document built awareness, but did not answer any questions.

Overall, the group felt that the White House message was focused on drug abuse, and not environmental issues. For instance, no one, including the pharmacists, could recall ever seeing a prescription that indicated a drug should be flushed down the toilet. The White House Statement builds awareness of the problem without adequately offering a solution and does not appear to understand the emerging environmental issues.

The group discussed the issues associated with disposing of drugs at a landfill. Penpraze discussed how drugs that are sent to a landfill get into the water system because the drugs percolate through the landfill and into the leachate. The majority of landfill leachate in Oregon is disposed of at municipal wastewater treatment plants, and these plants are not designed to remove microcontaminants such as pharmaceuticals. Disposing of drugs in a landfill is just another pathway for the drugs to get to the treatment plant and therefore into Oregon rivers and streams. The details regarding how leachate gets to a wastewater treatment plant should be stated in the report.

Penpraze emphasized that source reduction is the best way to tackle the problem. outcome.

Costs of not having a Drug Take Back Program

The group suggested that the report should incorporate the costs of not having a drug take back program. The group's suggestions included:

- Higher costs of wastewater treatment technology
- Higher costs of drinking water treatment technology
- Social cost of diversion of drugs
- Accidental poisonings
- Environmental costs – fish issues
- Loss of confidence in municipal water supplies.

PhRMA is coming to the next meeting. Gillaspie stated that the next meeting should be longer as funding issues and establishing priorities still have not been tackled. The May meeting will be from 9:30am to 3:00pm. Boudouris asked what happens after the June meeting. This will be discussed in the May meeting, as well as the June meeting.

Meeting follow up 'to do'

Contact ***Hospitals Without Harm***

Penpraze and Hill to determine the costs of wastewater treatment technology without an established drug take back program

Inventory day surgeries and Urgent Care Centers in Oregon – learn more about drug disposal practices

Learn more about the long term care pharmacies and their ability to take returned drugs from long term care facilities

Add information on a central warehouse owned by the Board of Pharmacy to the options

Small group – Penpraze, Burtt, Boudouris, Olson, Hill

Draft Agendas for Next Meetings

May 11, 2007 Meeting

Time extended from 9:30 am – 3:00 pm (30 minute break for lunch)

Presentation by Pharmaceutical Research and Manufacturers of America (PhRMA)

Product Stewardship preferences

Agreement on final program options

Volunteer group will develop 'strawman option'

Additional discussion on funding options

Review of second draft report

Focus on next steps - brainstorm

June 8, 2007 Meeting

Final Recommendations

Program Option

Funding

Final report signing

Next Steps

Celebration

Attending the meeting was:

- Leslie Wood-Pharmacy Research and Manufacturer's of America (PhRMA) (by phone)
- Rebecca Gold-Consumer Healthcare Products Association (CHPA) (by phone)
- Tony Burtt-Oregon Board of Pharmacy
- Jim Thompson-Oregon Board of Pharmacy
- Rebecca David-Oregon State Police
- Michael Stupfel-Oregon State Police
- Monica Hubbard-Oregon State University
- Sego Jackson- Northwest Product Stewardship Council / Snohomish County Solid Waste Management Division (by phone)
- Kevin Masterson-DEQ
- Tom Penpraze-City of Corvallis
- Abby Boudouris-DEQ
- Karen DeBaker-Clean Water Services (by phone)
- Jim Hill-City of Medford/ACWA
- Gerry Migaki-Oregon Society of Health System Pharmacists
- Brenda Bateman-Tualatin Valley Water District
- Sharon Olson-City of Eugene
- Teresa Huntsinger-Oregon Environmental Council
- Kristan Mitchell- Oregon Refuse & Recycling Association
- Janet Gillaspie-ACWA

Notes taken by LD Michaelis
3/09/07

10.2.5 MEETING 5: MAY 11, 2007

Oregon Pharmaceutical Drug Take Back Stakeholder Meeting

11 May 07

Salem, Oregon

MEETING SUMMARY

Attendance at end

INTRODUCTIONS

Janet Gillaspie facilitated the meeting. She asked if there were any questions about or changes to the agenda; none were voiced. The group introduced themselves.

Product Stewardship Program

Sego Jackson with Northwest Product Stewardship Council / Snohomish County presented a PowerPoint presentation ***"Proposal to Include Product Stewardship Program and Financing as Option in Oregon Report".*** A copy of the presentation is posted on the ACWA web site at www.oracwa.org. There is only one ongoing program for drug take back in the region, in British Columbia.It has been in operation since 1996. Drug manufacturers provide funding for the program; 123 manufacturers are billed for the operational costs. The costs are distributed using a tiered system based on annual sales or market share. The companies involved are 35% from generic manufacturers, 45% from name brands and 20% over-the-counter product manufacturers. Most of the companies involved in the take back program in British Columbia sell their products in Oregon and Washington.

Jackson stated that the pilot program he is involved with in Washington is moving towards a stewardship model.

Jim Hill asked about the viability of national legislation to set up a national drug take back program. Jackson stated that it would not happen. More entities need to apply pressure to the federal Drug Enforcement Administration (DEA) to get them to approve exemptions for reverse distributors or others to handle returned controlled drugs.

There was a discussion regarding the attempts to establish a national program for disposal of used electronic equipment. After approximately 4 years of trying, a national concept could not be agreed upon. States are now passing their own legislation for proper disposal of electronic equipment. California, Maine, and Minnesota have passed legislation; new legislation looks likely in Oregon and Texas.

Tony Burtt reminded the group that the BC program costs are low in part because there is no differentiation between controlled and noncontrolled drugs. He asked if there was any information regarding illegal drug diversion in the BC program. Also, what were the drivers that made the manufacturers take a stewardship role in building the BC program. Jackson indicated that he was told there have been no drug take back buckets lost or diverted. He was unsure what motivated the manufacturers to fund the take back program; however, the threat of establishing legislation is often a good motivator.

Leslie Wood said that PhRMA has concerns with litigation and liability of pharmacies in the US regarding a drug take back program. David Stitzhal stated that the risks needed to be managed at a minimal cost.

Gillaspie asked how the Washington pilot program would be moving toward a stewardship model. Jackson stated that they are currently looking for corporate sponsors. There will be legislation presented in the Washington 2009 Legislature regarding a drug take back program, he added.

Jackson advocates an industry financed stewardship program that is totally constructed by and managed by the manufacturers. Drug manufacturers could gain a lot of positive publicity mileage by establishing this type of program, he said. Scott Klag said that in the BC program all drug manufacturers that sell in BC must participate in a stewardship program.

PhRMA Presentation

Leslie Wood, Director of State Policy for PhRMA, presented PhRMA's position on a drug take back program in Oregon. A copy of her presentation is posted on the ACWA web site at *www.oracwa.org*. She stated that PhRMA has been rigorously studying the issue of pharmaceuticals in the water and how they affect patients, citizens and aquatic life. Their studies have determined that 99% of the substances found in the water are there due to human excretion. 1% of the pharmaceuticals in the water are due to direct application and 60 to 80 % of that amount comes from generic drugs. The effect of this small amount of drugs in the water would be the equivalent of one sugar cube dropped in a body of water equal to the water in four Olympic sized swimming pools. Patient use is the primary pathway of drugs in the environment. PhRMA follows the EPA in recommending that discarded drugs not be flushed, but mixed with water or kitty litter and deposited in the landfill.

PhRMA, in its studies, has used a human health screening analysis for 26 different types of pharmaceuticals. The studies did not include hormones in the evaluations. The results of the assessments determined that residues of drugs in the water present no appreciable risk to human health. Wood named five different studies that cited that environmental exposure presents little human health risk.

PhRMA stated that their preferred Drug Take Back option would be the method where all pharmaceuticals were returned to local law enforcement agencies. Law enforcement would provide the manpower and a hazardous waste vendor would pick up the discarded drugs. They have concerns with using identifiable mailing envelopes and the possibility of theft of drugs or fraud. The US Postal service does not allow for the mailing of drugs out of the chain of custody.

Wood said that a take back program would not be an effective use of resources if protecting the environment is the goal. Historically, there is only a 20% participation rate in other types of take back programs.

Burtt asked why the manufacturers would be supporting the British Columbia model if they felt the pollution from pharmaceuticals was insignificant. Wood stated that she did not have an answer. Stitzhal said that a drug manufacturer's representative from British Columbia had told him that the responsibility was spread evenly across the industry, due to concerns with drug diversion, abuse, and pollution issues. The BC program started voluntarily, but is now backed by legislation.

Wood emphasized that consumer education is important in disposing of drugs effectively and that consumers should be informed of the EPA-approved methods of disposal. Klag asked Wood if PhRMA knew what their consumers wanted. She advised that she did not know. PhRMA's position is that drug abuse is a community problem, not a manufacturer's responsibility. Take back programs should be funded at the community level, she said.

Stitzhal reminded the group that the makers of OxyContin have to pay a fine due to abuse of their product. Wood stated that there are bad players that have to abide by the rules and re-emphasized that EPA has rules for proper drug disposal. Group members offered that garbage disposal technology is changing so drug disposal to a landfill may not be prudent in the future.

There was discussion regarding other industries that are involved in recycling or take back programs. The PhRMA presentation advocated using a system similar to battery returns, and battery recycling programs are funded by the manufacturers. Klag said that Metro is looking at paint manufacturers to fund a paint take back program nationally.

Gillaspie said that the group had determined that using law enforcement would not be a good drug take back option. She asked how Oregon could partner with PhRMA to find an agreeable solution. Wood stated that the generic and consumer products industries need to be represented in this discussion. There is also the ongoing concern about DEA regulations on controlled substances. There are also concerns with abuse in a mail back program if DEA waivers can be obtained.

Kristan Mitchell would like PhRMA to provide information on their studies that show landfill leachate is not a factor in pollution. She agreed that education of the consumer is paramount.

Wood stated that PhRMA's members are very focused on providing prescriptions to the uninsured. PhRMA has toxicologists studying the issue of drugs in the water, but the science shows that there is little risk to human health. They are using studies to determine if there is a problem. There is a task force established by PhRMA and staffed by the manufacturers that evaluates the toxicology reports. Burtt asked how the issues are funded. Wood stated that she did not know.

Burtt suggested that perhaps drugs in the environment are a burgeoning problem that we could head off; industry should react proactively.

PhRMA is trying to determine how many drugs are being stock piled in homes across the US. Wood will provide info on their research on this issue. PhRMA's position is the stockpiling of drugs is a community issue.

Hill asked if there was a risk to aquatic life would PhRMA be involved in finding a solution. Wood stated that research is needed to confirm there is a problem. Jackson asked how long PhRMA had been involved in researching the issue of drugs in the water; Wood did not know.

Gillaspie asked if a product stewardship option should be added to the draft report; no opposition was voiced. Also, what do studies show about drugs in leachate? Gillaspie suggested spending part of the task force's funds to have someone review research and analyze data. She will hire a grad student, with Hill, Mitchell, and Brenda Bateman's input, to review data on landfill leachate. The group agreed.

Gillaspie proposed writing a letter to PhRMA, the generic manufacturers' group and the consumer products group asking for their recommendations for an Oregon drug take back program. Jackson asked if the letter should be more of an invitation to the groups to help set

up a pilot program in Oregon. Teresa Huntsinger also suggested finding partners – other states – to help promote the cause and share ideas and/or responsibilities.

Burtt asked Wood to e-mail responses to the questions asked today:

1. PhRMA data on percentages of drugs in water excreted vs. flushed.
2. Social science data/research
3. What program would work best for the manufacturers
4. PhRMA data on leachate

Straw Proposal

Gillaspie revisited the Drug Take Back Program group's charter and refreshed the groups' memory about the goals of the group. The Stakeholder Group scope of work includes… ***"4) Develop stakeholder group consensus on the best drug take back program for Oregon that is effective, includes both controlled and routine drugs, and is as economical as possible"***.She reminded the group that they set their decision making process as "modified consensus minus one".

She highlighted some of the key issues for the group to consider in reviewing the straw proposal:

1. Is legislation necessary?
2. Does the group agree that it should be staged, with a mail back option first and collection in the second phase?
3. Is the correct state agency to host this program the Oregon Department of Human Services – Oregon Public Health Division?
4. Does the group agree with the funding mechanism?
5. Are the interim actions (hospital survey, development of Best Management Practices - BMPs) reasonable?

Hill reviewed the straw proposal that was distributed to the group prior to the meeting. The key part is getting the DEA exemption for the reverse distributor. The first phase of the program would be a mail back program; the second phase a collection box system at the pharmacies. Funding would be a fee on the drug manufacturers and suppliers. Hospitals and larger long term care facilities would be required to use BMPs.

Huntsinger asked why the mail back option first, then collection boxes. Hill stated that the mail back system is easier to implement, cheaper and more available to rural areas. Bateman asked where the mailers would be sent. The mailers would go directly to a reverse distributor or hazardous waste incinerator, if the DEA exemption is in place. Liquid drugs are not likely to be returned in a mail back program.

Jackson asked if wastewater treatment plant effluent could be treated to remove pharmaceuticals. Hill stated that wastewater treatment plants would be required to use a microfiltration followed by a reverse osmosis system. This type of system requires a very high use of energy and generates a salty brine that is difficult to dispose of.

Jackson stated that the reverse distributor in the Northern California case has received a verbal okay from the DEA to receive mailed back pharmaceuticals. The physical letter is expected shortly.

Establishing a fee on drug manufacturers that is collected by the Board of Pharmacy will require legislation. It is likely that legislation will take years to pass; additional taxes will most likely not be approved, added Burtt.One suggestion was that manufacturers and suppliers wishing to sell in Oregon would have to have a program in place to deal with discarded drugs. Klag said that the electronics manufacturers recycling bill took three attempts before it passed.

Opinions on the straw proposal from the group included:

- Product stewardship model can work. It should focus on any company that ships drugs into Oregon and require an environmentally safe, convenient disposal system. Some performance standards for the program will be needed. To ensure the program is put in place, a legislative backdrop that puts a state-operated program in place if the manufacturers and suppliers do not step up is needed. (Many members of the group agreed with this approach as being superior to that included in the straw proposal)
- Political pressure is needed to ensure the product stewardship model moves forward.
- Find a champion in the industry that is interested in building a product stewardship program.
- Discuss this issue with legislators and learn their ideas.
- The "call to action" needs to be improved; there needs to be a more compelling case made in the final report.
- There needs to be a "Plan B" if there is no DEA exemption forthcoming.
- Company shareholder resolutions are an effective tool to get manufacturer's to address issues of concern.

The group agreed to recommend that the drug manufacturers and suppliers operating in Oregon be asked to institute a product stewardship program to handle the unwanted or unused drugs in Oregon.

Ann Jackson of the Oregon Hospice Association said that the industry has concerns on the drug take back issue. She suggested applying for grants to get the program started. The national hospice groups are not involved in the issue; state organizations are more concerned. 60% of all hospice care is in individual homes. It was suggested that hospice groups could place political pressure on pharmaceutical manufacturers to participate in a drug take back program.

The group discussed what the recommendation should be if there is no DEA exemption for the programs currently moving forward in Washington, California, and Maine. The group concluded that a program that relied on law enforcement involvement, and that followed the current EPA recommendations to put unwanted drugs in the garbage with an education and outreach campaign would be the only other alternative.

Report Review

The group discussed the current draft report. Items to be revised or added in the report included:

- Add product stewardship option (Sego Jackson will assist in the writing)
- Hire a qualified individual to complete a literature review regarding the presence or absence of pharmaceuticals in landfill leachate
    - Gillaspie will draft a scope of work and work with Hill, Mitchell, and Bateman to review

- A section on hospice care should be added. Ann Jackson can assist with this.
- Gillaspie should sent a letter to PhRMA, the generic manufacturers, and the consumer products group inviting them to suggest what a model product stewardship system might be and reflecting that many of their members currently participate in the BC system
- Improve the "call to action" aspects of the report – this might be accomplished in the Executive Summary or other tools to "tell the story"

Next Steps

The strategy of promoting a product stewardship model for the Oregon Drug Take Back program was agreed to by the group. Tony Burtt will take the lead in revising the straw proposal to reflect the will of the group.

The final report will be distributed at the June 8th meeting. All stakeholders will have between June 8 and July 13 to vet the report and its recommendations with their group, driving towards an agreement from their group to sign the final report. After the report is finalized, other groups will be asked to endorse the recommendations of the report.

Other items that need to be accomplished:

- Develop a lobby strategy
- Inform and involve the Oregon congressional delegation
- Get John Horton, Associate Deputy Director for State and Local Affairs White House Office of National Drug Control Policy involved
- DEQ will take the lead on the BMP survey for hospitals
- BMPs need to be developed for long term care facilities

Next meeting

Friday, June 8, 2007

9:30am to Noon

Willow Lake Treatment Plant meeting room

The group set one additional final meeting for July 13, 2007 from 9:30 am – noon at the City of Salem Treatment Plant.

Attending the meeting was:

- Leslie Wood-PhRMA
- Abby Boudouris – DEQ (by phone)
- Dave Leland – Oregon DHS, Drinking Water Program
- Tony Burtt-Oregon Board of Pharmacy
- Rebecca David-Oregon State Police
- Scott Klag - METRO
- Sego Jackson- Northwest Product Stewardship Council / Snohomish County Solid Waste Management Division
- Karen DeBaker-Clean Water Services (by phone)

- Jim Hill-City of Medford/ACWA
- Brenda Bateman-Tualatin Valley Water District
- Teresa Huntsinger-Oregon Environmental Council (OEC)
- Kristan Mitchell- Oregon Refuse & Recycling Association
- David Stitzhal - Northwest Product Stewardship Council
- Janet Gillaspie-ACWA
- Laura Michaelis – ACWA

Notes taken by LD Michaelis
05/11/07

10.2.6 MEETING 6: JUNE 15, 2007

Oregon Pharmaceutical Drug Take Back Stakeholder Meeting

15 June 07

Salem, Oregon

MEETING SUMMARY

Attendance at end

INTRODUCTIONS

Tom Penpraze and Tony Burtt co-chaired the meeting. Janet Gillaspie facilitated the meeting. She asked if there were any questions about or changes to the agenda; none were voiced. The group introduced themselves.

Drug Take Back Program Proposal

Gillaspie asked for comments on the proposed stakeholder recommendations from the industry representatives – Pharmaceutical Researcher and Manufacturers of America (PhRMA) and the Consumer Healthcare Products Association (CHPA). The Generic Pharmaceutical Association (GPhA) did not respond to the Group's request for feedback.

Leslie Wood of PhRMA stated that her organization does not agree with the recommendation that Oregon institute a drug take back program using the British Columbia program as a model; they do not believe that the costs in the Oregon program would be the same. Also, it is unlikely Drug Enforcement Administration (DEA) would allow such a program to be operated due to concerns with controlled drugs.

Holly Sears of the Oregon Refuse & Recycling Association stated that she felt there was not enough information for her organization to endorse the recommendations of the group. She stated that one-half of Oregon's refuse goes to the Arlington landfill where the leachate is handled by evaporation and not discharged to Oregon waterways.Drugs in the water are most likely there through excretion. Tom Penpraze of the City of Corvallis reminded the group that leachate at other refuse sites, especially in wet Western Oregon, is piped or trucked to wastewater treatment plants.

Wood was asked if the DEA changed its policy for handling of controlled drugs, would PhRMA change their position. She stated that PhRMA's position would not change; the science does not support it. The group questioned PhRMA about a variety of issues incorporated in a landfill leachate report prepared by PhRMA and forwarded to the Drug Take Back Program group.

Gillaspie asked when PhRMA's comments regarding the recommendation proposal would be ready. Wood responded that some definitions in the report are unclear and need to be better defined. There are also some facts that are incorrect and need to be corrected. The report needs to reflect the dissension of some of the participants involved and the problem statement should be more clear and concise. Gillaspie stressed that she was interested in PhRMA's comments to ensure that the report was as accurate as possible.

Paul Larsen of the Consumer Healthcare Products Association stated that his organization represents many companies and they are committed to being involved with the Oregon

Drug Take Back Program group. However, they are just now getting input from their member companies. He requested an extension of time past the July 13th date for CHPA to respond. They would be unable to endorse the recommended proposal without more input from their members.

Larsen and Wood both were unable to comment as to why the Generic Pharmaceutical Association has not participated in this process. The group agreed that Gillaspie should make another phone call and send another letter to GPhA requesting their involvement.

Penpraze asked for additional comments on the ***"Proposal for Drug Take Back Program"*** report. The report recommends and outlines a manufacturers' stewardship model with Best Management Practices (BMPs) crafted for hospitals and long term care facilities. There were concerns that there will be no forward progress of this program for 2 years if the group waits for the 2009 Oregon Legislature to be in session. Members questioned how to motivate the private sector. Retailers have been interested in this issue because their customers have asked for ways to dispose of unwanted drugs.

The group discussed the parallels between product stewardship in the drug industry and the electronics industry. The electronics industry is now facing different versions of a product stewardship program in many different states. Faced with that, the electronics industry is now taking the lead in developing programs to recycled unwanted electronic products.

Tony Burtt, Oregon Pharmacy Board, said that this proposal makes some assumptions, but there is insufficient science to back those assumptions. There are concerns with the amount of drugs in the water from excretion versus disposal by flushing. He also questioned if landfill disposal was perhaps an acceptable practice for unwanted drugs. Perhaps more data needs to be collected to verify that drugs are entering the waterways from flushing and landfill leachate.

Penpraze stated that it is possible that wastewater treatment plants would stop accepting leachate from refuse sites if there are concerns about it containing drugs.

Scott Klag, METRO, suggested that the issues of prescription drug addiction and accidental poisonings should be emphasized in the report. Gillaspie reminded the group that this program will not solve the water quality concerns with pharmaceuticals; it is just a part of the solution.

Jim Thompson with the Oregon State Pharmacy Association asked how consumers would be motivated to participate and suggested that a significant education effort would be required. Would consumers truly go out of their way to dispose of drugs in an alternative way? It is possible that the program will be expensive to establish and then consumers will not participate. People have been taught for years to flush their unwanted drugs, now they will have to be "un-taught".

Members stated that consumers can be "un-taught". Cities have been successful in changing habits about putting oil in storm drains, for example. Kevin Masterson, DEQ, said that switching drug disposal from flushing to landfill could switch the contaminants from the waterways to landfill leachate. Klag emphasized that in order for the program to be successful, it must be convenient to use.

It was suggested that the report needs a stronger statement that education will need to be statewide and will need to be collaborative. Wood said that more information on the BC take back program model should be included in the recommendations portion of the report. Gillaspie agreed and said that the report would be amended to include more information.

In response to a question, the group discussed how the take back program in King County Washington began as a cautionary action, motivated from the hazardous waste angle. The group discussed whether expected social outcomes should be listed in the report. The group agreed that they should be listed.

Sears cautioned that there could be a lot of money spent on a program that may not achieve any change in water quality and suggested that education would be a better way to spend funds. For her group, the science needs to be there before a large amount of money is spent to establish a take back program. Thompson suggested setting up and polling consumer focus groups to determine how people are disposing of their unwanted drugs and how they feel about drug disposal. Gillaspie reminded all that the funds for the group are limited and taking on such a poll is outside the scope of this project.

Burtt said that more scientific information might be needed in order to get more stakeholders to endorse the proposal. Gillaspie stated she felt that the group was losing momentum and needed to finalize a report. Brenda Bateman, Tualatin Valley Water District, echoed this opinion by stating that the report should reflect the concerns held in the beginning, emphasize that this is just a beginning, but that also, a lot has been accomplished.

Brett Hulstrom, City of Portland BES, said that hazardous waste issues are historically a parallel to this issue. Having a place to properly dispose of unwanted drugs is the right thing to do. We may not know, with today's technology, that there are problems in our soil and water.

Changes to the report

Gillaspie will edit the report to add/amend:

1. A stronger problem statement
2. More information on water quality issues
3. A paragraph on expected social outcomes.

The revised recommendations will be distributed on Monday, 6/18/07 and comments will be due back by Friday, 6/22/07.

Literature Review

Dr. Jeff Nason of OSU has proposed a cost of $2,700 for the leachate literature review; Gillaspie had budgeted $1,500. She questioned what the will of the group was. Is the research still valuable? There was discussion regarding the structure of the report. The group agreed that the information is still valuable and relevant and agreed with the proposal to spend $1,500 for a report to be delivered in the next 30 days. Sears will ask her national counterpart organization if they have any leachate research that is applicable.

The group wanted the report to be sorted by active and inactive landfill sites, and those sites with leachate collection and without leachate collection.

Final Report

The group discussed the final report. Gillaspie welcomed editorial comments to be submitted to her.

After the discussion, the Group asked that these changes be made:

- Clarify anticipated water quality impacts
- Include the OSU landfill study
- Include Final Recommendation and Executive Summary

Executive Summary

Gillaspie distributed a draft executive summary prepared by a professional writer. The group asked that these changes be made:

- Study references should be in the text; the source from the full report should be referenced
- Use "pharming" instead of "phishing"
- Establish a compelling reason why the 3% water quality issues must be addressed

Next Steps

Gillaspie distributed a draft PowerPoint presentation and asked for comments. She has prepared the presentation to assist group members in making presentations on the draft recommendations to their organization or others.

Gillaspie also asked for additional groups that might be likely to endorse the group's recommendations. The suggestions included:

- Columbia and Willamette Riverkeepers
- Farm Bureau
- Water 4 Life
- Oregon Water Resources Congress
- Oregon Trout
- Save Our Wild Salmon
- Watershed Councils
- Oregon Department of Fish and Wildlife (ODFW)
- Drug Enforcement Administration (Bill Etter)
- Oregon Poison Center
- Drug Prevention Coordinators
- US Fish & Wildlife
- NOAA Fisheries
- PTAs in Oregon
- AARP

The Executive Summary is what supporters will be endorsing. Comments on the final report are needed by June 29th.

Next meeting

Friday, July 13, 2007

9:30am to Noon

Willow Lake Treatment Plant meeting room

Attending the meeting was:

- Leslie Wood-PhRMA (by phone)
- Paul Larsen-CHPA (by phone)
- Dave Leland – Oregon DHS, Drinking Water Program
- Tony Burtt-Oregon Board of Pharmacy
- Rebecca David-Oregon State Police
- Scott Klag-METRO (by phone)
- Ann Tweedt-Bristol Meyers Squibb (by phone)
- Jim Hill-City of Medford/ACWA
- Brenda Bateman-Tualatin Valley Water District
- Tom Penpraze-City of Corvallis
- Holly Sears- Oregon Refuse & Recycling Association
- Kevin Masterson-DEQ
- Jim Thompson-Oregon State Pharmacy Association
- Brett Hulstrom-City of Portland Bureau of Environmental Services (BES)
- Jennifer Seely-Kaiser Permanente
- Janet Gillaspie-Oregon Association of Clean Water Agencies (ACWA)
- Laura Michaelis – Oregon Association of Clean Water Agencies (ACWA)

Notes taken by LD Michaelis
06/15/07

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10.2.7 MEETING 7: JULY 13, 2007

Oregon Drug Take Back Stakeholder Meeting

13 July 07

Salem, Oregon

MEETING SUMMARY

Attendance at end

INTRODUCTIONS

Co-chair Tom Penpraze chaired the meeting; Co-Chair Tony Burtt participated by phone. Janet Gillaspie facilitated the meeting. She asked if there were any questions about or changes to the agenda; none were voiced. The group introduced themselves.

Trade Associations Comments

Gillaspie asked for input from Paul Larsen, Consumer Healthcare Products Association (CHPA), regarding the Stakeholders' recommendation.He stated that the organization was not in a position to endorse the program, as they are unsure of all the details. They still have many questions and their endorsement would depend on the answers to the questions. Jim Hill, City of Medford/ACWA, asked Larsen if CHPA had been asked to endorse programs from other states – he said that he was unaware of any requests.Gillaspie requested Larsen find out if there are other states that have presented them with a similar approach. Paul Larsen will be replacing Rebecca Gold as the contact for CHPA.

Clement Cypra of Pharmaceutical Research and Manufacturer's of America (PhRMA) was asked what liability costs Leslie Wood of PhRMA was referring to when she said that the Oregon Drug Take Back program had no hard and fast costs available, and that liability costs were not included in the program cost estimates. He stated that she was referring to possible issues with fraud and theft due to substances being stolen at a point in the supply chain. PhRMA is concerned with drugs being diverted. The British Columbia program is not a valid comparison as Canada does not have product liability laws and there is no program like the federal Drug Enforcement Administration (DEA), he added. PhRMA advocates disposal of unwanted drugs in landfills as outlined by the EPA.

Gillaspie asked Cypra to provide a statement outlining PhRMA's position with emphasis on their liability concerns. He stated that the Oregon Drug Take Back program as outlined cannot be implemented under the current laws and regulations. Cypra stated that for the record PhRMA is opposed to the Oregon Drug Take Back program as outlined. The costs are prohibitive, especially if other states follow Oregon's lead. This is a personal conduct issue, not an issue of environmental concern. PhRMA will not endorse the program in any form. Gillaspie thanked him for his input.

Gillaspie asked the group for their comments on the final proposal. Brenda Bateman reminded the participants that this proposal will not address all the drug disposal issues. Tom Penpraze suggested making the program elements clearer. Assumptions and details should be transparent; nothing should be hidden or overstated, he said.

The group reviewed the proposal language. The recommendations included clarifying the water quality impacts of the program, and including a reference to the landfill study.

Meeting participants said that they were waiting for the final proposal to be completed before presenting it to their organizations. Hill stated the ACWA had already endorsed the proposal.

Technical Literature Review

Dr. Nason of OSU is reviewing existing technical information and is expected to present his report mid-August. His report will be an attachment to the final Drug Take Back program report.

Executive Summary

Gillaspie stated that the group needed to focus on the changes needed to the summary, as there is money in the budget for only one more draft from the technical writer. The consensus was there was redundancy in the summary and that there was no need for detailed citations in the summary as they would be in the final report. The term "avoidable" should be used instead of "accidental" when referring to poisonings as it implies that they are preventable.

There was discussion regarding clarifying the costs vs. benefits clearly in the summary. It was decided instead of emphasizing the costs, the summary should emphasize the societal gains. Examples of controlled drugs should be listed for comprehension.

SB 737 details will be added to the report and referenced in the summary.

The water quality and societal benefits sections will be rewritten by Gillaspie and sent to members for comments. The summary and report should reflect that PhRMA opposes the Drug Take Back program.

Next Steps

Members discussed who would approach which organizations for their endorsement of the Oregon Drug Take Back program proposal. The following contacts were agreed to:

Named Members that Did Not Participate & Others

ORGANIZATION	KEY CONTACT	ASSIGNED TO?
Oregon Sheriffs' Assoc.	Dave Burright	Becky David – OSP
OR Association of Chiefs of Police	Kevin Campbell	Becky David – OSP
Covanta Marion	Kelly Champion	Brenda Bateman
Clackamas CO. Medical Examiner	Jeff McLennan	Jim Thompson
Oregon Water Utilities Council	Brenda Bateman	Brenda Bateman

Other Stakeholders

Oregon Congressional Delegation

	STAFF	*ASSIGNED TO?*
Wyden		Jim Hill
Smith		
Blumenauer	Hillary Barbour	Brenda Bateman
Wu	Ann Richardson	Brenda Bateman
DeFazio		Tom Penpraze
Walden		Jim Hill
Hooley		Teresa Huntsinger

Federal/State/Local Agencies

Federal

Agency	Key Staff	Assigned to?
Federal		
DEA	Bill Etter	Janet Gillaspie
EPA – OR Operations	Janet Gillaspie	ACWA
NOAA Fisheries		ACWA
US Fish & Wildlife		Jim Hill

State

Agency	Key Staff	Assigned to?
DEQ/EQC		Abby Boudouris/Kevin Masterson
Board of Pharmacy		Tony Burtt
Public Health Division	Public Health Advisory Board	Dave Leland
OSP		Becky David
Oregon Dept. of Fish & Wildlife		Becky David

Local

ACWA Conference	Scheduled 7/27/07	Tom Penpraze
LOC Water/Wastewater Committee		Tom Penpraze
Oregon Water Utilities Council		Brenda Bateman
Council of Local Health Officials		Dave Leland
Oregon Water Resources Congress		Tom Penpraze
Watershed Councils / John Moriarty		Request presentation for fall OWEB conference, Teresa Huntsinger
OWEB		Jim Hill

Environmental Public Interest Groups

Columbia Riverkeeper		Teresa Huntsinger
Willamette Riverkeeper		Teresa Huntsinger
Save our Wild Salmon		Teresa Huntsinger
Oregon Trout		Teresa Huntsinger

Other Groups

PTA – Statewide Group		
Oregon AARP		Janet Gillaspie
Oregon Farm Bureau		Teresa Huntsinger
The Collaborative on Health & Env't		Teresa Huntsinger
Physicians for Social Responsibility		Teresa Huntsinger
Oregon Medical Association		Gerry Migaki
NW Prod Stewardship Council		Abby Boudouris, Sego Jackson, and Dave Stitzhal
OSPIRG		

The group also suggested that the tribal nations in Oregon be approached for their support. Also, the staff at Multnomah County and the City of Portland working on toxic reduction efforts should also be approached for their endorsements.

Gillaspie suggested that the way to approach the potential endorsees would be to inform them of the program first by using the summary, report, and recommendations. If possible, use the PowerPoint slide presentation, modified for the specific audience. Ask the group to endorse the concept by writing an endorsement letter. Emphasize that no financial resources are required. The endorsement letter should be addressed to the Oregon Drug Take Back stakeholder group c/o ACWA. Gillaspie will craft a letter template.

Boudouris asked what happens after the endorsements. Gillaspie stated that that is unknown, but will be addressed at the next meeting in October. A slide should be inserted into the PowerPoint presentation outlining what the next steps will be.

Process Review

Gillaspie reviewed the work of the Stakeholder group over the year and solicited comments from the group about how the process had worked. The comments included:

- The industry representatives should have been identified sooner. The process felt rushed.
- Things ran smoothly considering the group's change in focus.
- Having meetings during the Oregon Legislative Session hindered some people from attending.
- It was a good idea to have a graduate student do the research. Monica Hubbard helped a great deal.
- There was a good cross section of agencies involved.
- The collaborative nature of the process was a plus.

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Next meeting

Friday, October 19, 2007

9:30am to Noon

Willow Lake Treatment Plant meeting room

Salem, Oregon

Attending the meeting was:

- Clement Cypra – Pharmaceutical Research and Manufacturers of America (PhRMA) (by phone)
- Jim Thompson – Oregon State Pharmacy Association
- Tony Burtt – Oregon Board of Pharmacy (by phone)
- Brett Hulstrom – City of Portland Bureau of Environmental Services
- Abby Boudoirs – Department of Environmental Quality (DEQ) (by phone)
- Dave Leland – Oregon Department of Human Services (DHS), Drinking Water Program
- Jenny Seeley – Kaiser (by phone)
- Rebecca David – Oregon State Police
- Sego Jackson – Northwest Product Stewardship Council / Snohomish County Solid Waste Management Division (by phone)
- Paul Larsen – Consumer Healthcare Products Association (CHPA) (by phone)
- Jim Hill – City of Medford/ACWA
- Brenda Bateman – Tualatin Valley Water District
- Tom Penpraze – City of Corvallis
- Gerry Migaki – Providence Health Systems
- Janet Gillaspie – ACWA
- Laura Michaelis – ACWA

Notes taken by LD Michaelis
07/13/07

10.3 *Appendix B: Literature Review: Occurrence and Fate of Pharmaceutical Compounds in Landfill Leachate*

Literature Review: Occurrence and Fate of Pharmaceutical Compounds in Landfill Leachate

Prepared for

Oregon Association of Clean Water Agencies

by

Jeffrey A. Nason, Ph.D.

August, 2007

ABSTRACT

In light of the recent guidance issued by the White House Office of National Drug Control Policy, directing consumers to dispose of unwanted prescription drugs in household trash, a review of the available research focused on the occurrence and fate of pharmaceutical compounds in landfill leachates and groundwater contaminated by unlined landfills is presented. Research, primarily outside the U.S., has detected and quantified pharmaceutical compounds in landfill leachate and in groundwater down gradient of leaking and unlined landfills at concentrations on the order of ng/L to mg/L. The highest concentrations (> 100 ìg/L) have been found in instances where pharmaceutical production waste was disposed of at the site; concentrations on the order of ng/L to ìg/L were more typical of municipal solid waste landfills. According to theoretical calculations and a limited amount of field data, the total load of all pharmaceutical compounds to surface water via landfill leachate is predicted to be small (< 1%). However, the likelihood that drugs disposed of in landfills will ultimately end up in surface water is compound specific.

INTRODUCTION

In February of 2007, the White House Office of National Drug Control Policy released guidance on the proper disposal of unused or unwanted prescription drugs (ONDCP, 2007). The guidance directs consumers to dispose of the unused drugs in household trash or to take advantage of drug take-back programs, rather than flushing the drugs down the toilet. Although a great deal of research has focused on the fate of pharmaceutical compounds in municipal wastewater (Jones *et al.*, 2005), relatively little is known about the occurrence, transformation and fate of pharmaceutical compounds in landfills. Bellante *et al.* (2003) argue that the small number of studies is a result of the broad variety of pharmaceutical compounds and the relatively small amounts of pharmaceutical compounds present in municipal solid waste. This document is a review of available technical literature regarding the absence or presence of pharmaceuticals in landfill leachate and groundwater below unlined landfills. Previous literature reviews focused on pharmaceuticals in aquatic systems (Heberer, 2002), household drug disposal (Bellante *et al.*, 2003; Bound and Voulvoulis, 2005), household hazardous waste (Slack *et al.*, 2005) and pharmaceuticals in landfill leachate (Metzger, 2004), along with the U.S. EPA's new website focused on pharmaceuticals and personal care products (USEPA, 2007), were extremely useful in identifying the pertinent literature and placing it in the context with the larger problem of pharmaceuticals and personal care products in the environment.

Occurrence of Pharmaceuticals in Landfill Leachate

To date, a limited number of studies have investigated the presence or absence of pharmaceutical compounds in landfill leachate and/or groundwater contaminated by landfill leachate. The work that has been done has focused on a wide variety of prescription and non-prescription drugs and their environmental metabolites. Studies have examined both active and closed landfills and those with and without leachate collection systems. As noted by Metzger (2004), comparisons of concentrations between landfills are impossible due to the varied nature of waste disposed of in municipal solid waste landfills, as well as leachate dilution by rainwater. What the available research does convey, however, is the range of concentrations that have been measured. What follows is a review of the pertinent literature in this area. A data table summarizing the specifics of each study (drugs, concentrations, landfill characteristics, etc.) is contained in Appendix A.

Eckel *et al.* (1993) re-analyzed gas chromatography/mass spectrometry data from a sample collected in 1984 as part of an earlier study. The sample was collected 300 m down gradient from an unlined Florida landfill that was active in 1968 and 1969, receiving waste from two large naval bases. It is believed that waste from a large hospital located on one of the bases contributed to the waste disposed of at the site. As a result of the analysis, the sedatives pentobarbital and meprobamate and the anticonvulsant phensuximide were identified (but not quantified) in the groundwater. The investigators drilled a new well adjacent to the 1984 sampling location and analyzed the groundwater for pentobarbital. The compound was found at a concentration of 1 ìg/L.

Holm *et al.* (1995) sampled groundwater at depths from 5.5 to 10 m down gradient (0-260 m) of an unlined Danish landfill that accepted approximately 85,000 tons of waste from pharmaceutical manufacturing over the course of 13 years prior to the closure of the landfill in 1977. Six sulfonamides (sulfanilic acid, sulfanilamide, sulfaguanidine, sulfadiazine, sulfadimidine, sulfamethizol) and three byproducts of their production (aniline, ***o***-chloroaniline, ***p***-chloroaniline), one barbiturate (5,5-diallylbarbituric acid), an analgesic (propyphenazone), an intermediate in the production of meprobamate (2-methyl-2-***n***-propyl-1,3-propanediol), and an anti-foaming agent used in pharmaceutical production (tri-(2-methylpropyl)-phosphate) were found in the groundwater; concentrations ranged from less than 1 ìg/L to 18 mg/L across the compounds, sampling locations and depths.

Ahel *et al.* (1998) sampled solid waste and underlying soil (1 m) from three different locations within an active unlined landfill in Croatia. Solids were analyzed for several different chemicals. The analgesic propyphenazone was found in the soil at concentrations up to 0.1 mg/kg in the soil and 10 mg/kg in the solid waste itself. Isopropylidene carbohydrate derivatives from the manufacture of Vitamin C were also found at concentrations in excess of 10 mg/kg in the solid waste and up to 1 mg/kg in the underlying soil. The authors link these concentrations to disposal of pharmaceutical production waste, rather than from disposal of municipal refuse.

In a subsequent study at the same site (Ahel and Jelicic, 2001) the authors also examined the concentrations of pharmaceutical compounds in the landfill leachate and groundwater underlying the landfill. Three phenazone analgesics (propyphenazone, aminopyrine, and antipyrine) were detected in the solid waste, leachate, underlying soil and groundwater. Propyphenazone was found at concentrations up to approximately 50 ìg/L in the leachate and in the groundwater, suggesting that the compound is highly mobile and persistent in the environment. Aminopyrine was also present in the leachate (up to 16 ìg/L) and the groundwater (up to 36 ìg/L). However, concentrations declined rapidly from "hot spots" of the compound within the landfill. Antipyrine was found in the leachate at trace levels (< 50 ng/L).

Paxeus (2000) quantified approximately 200 organic compounds from three landfills in Sweden. Landfill A, active since the mid 1970's, received mixed waste (incineration, wet screenings from a wastewater treatment plant, industrial) that did not appear to include household waste. Landfill B, active since 1964, received mixed waste (sewage sludge, industrial, construction, household). Landfill C, closed at the time of the study (operated 1938-1978) received all kinds of waste (household, industrial, chemical, construction, sludges, cadavers, etc.). While not explicitly stated, it appears that these three landfills were equipped with leachate collection systems as yearly leachate production rates were cited. Three antiphlogistics were found in leachate from these landfills. Ibuprofen was found at a concentration of 8 ìg/L in leachate collected from landfill A, phenazone was found at concentration of 37 ìg/L in leachate collected from landfill C, and isopropylphenazone was found at concentrations of 1.1 ìg/L and 49 ìg/L from leachate collected at landfill A and landfill C, respectively.

Schwarzbauer *et al.* (2002) took advantage of a breach in the liner of a landfill in Germany, sampling seepage (leachate) and leakage water (collected in a mining system below the landfill, but above the water table) for a wide variety of organic compounds. Two analgesics (ibuprofen and propyphenazone) and the environmental metabolite of a blood lipid regulator (clofibric acid) were detected in both of the leachate samples and the leakage sample. The concentration of propyphenazone ranged from 110-140 ìg/L in the leachate and in the leakage water, again indicating the compound's persistence in the environment. Although detected in the leachate and the leakage water, ibuprofen and clofibric acid concentrations were not quantified.

In a follow-up study at the same site, Heim *et al.* (2004) looked more in depth at the persistence of some organic chemicals in the groundwater surrounding the leaking landfill. Ibuprofen, propyphenazone and clofibric acid were detected in the groundwater (up to 500 m from the edge of the landfill) and in the leakage water collected from the exit of the mine shaft running below the landfill (at a distance of approximately 2 km from the landfill). Propyphenazone was present at concentrations of up to 1.4 ìg/L in the groundwater adjacent to the landfill and up to 100 ng/L in the leakage water. Clofibric acid was found at concentrations up to 1.1 ìg/L in the groundwater and up to 55 ng/L in the leakage water. Concentrations of ibuprofen in the groundwater were not reported, but the compound was present in all leakage water samples at trace levels (< 5 ng/L). Concentrations in the groundwater and leakage water were 100-1000 times less than the concentrations measured in the leachate (Schwarzbauer *et al.*, 2002), but their presence indicates that the compounds are mobile and persistent in the environment.

Barnes *et al.* (2004) tested for 76 organic wastewater contaminants in groundwater wells down gradient of a closed landfill in Norman, Oklahoma. The unlined landfill was operated from 1920-1985, at which point it was closed, capped with clay and vegetated. During operation, the landfill received residential and commercial waste, along with some hazardous waste. Wells varied from 3 ft to 584 ft away from the landfill. Of the 76 compounds that were analyzed, 21 were antibiotics or metabolites of antibiotics, and 18 were human prescription or non-prescription drugs or metabolites. One antibiotic (lincomycin) and one metabolite of a human non-prescription drug (cotinine) were detected in the wells. Lincomycin was found at concentrations ranging from < 0.05 to 0.1 ìg/L and cotinine was found at concentrations ranging from < 0.05 to 0.13 ìg/L.

Schneider *et al.* (2004) measured the concentrations of 28 different pharmaceutical compounds in the leachate from two active municipal landfills in Germany that received household waste. While not explicitly stated, the fact that leachate production rates were listed suggests that both landfills were lined. Concentrations of the various compounds ranged from ng/L to ìg/L

levels, with the highest concentrations being found for several analgesics (***e.g.***, ibuprofen, propyphenazone, and phenazone) and an anticonvulsant (primidone). Details of the chemical concentrations can be found in Appendix A. The distribution and quantity of these compounds in the landfill leachates was compared to the distribution and quantity in municipal wastewater influent. It was found that the distributions were quite different, and that the contribution of the leachate stream to the total load of pharmaceuticals in the influent of the wastewater treatment plant was small.

Foreign Literature

The specifics of two studies published in German were summarized in a literature review in English by Metzger (2004). As reported in that article, Schneider *et al.* (2001) measured the concentrations of several pharmaceutical compounds in two municipal landfills in Germany. Quantified drugs included clofibric acid, diclofenac, ibuprofen, indomethacin, pentoxyfylline and primidone; concentrations ranged from 1 to 20 ìg/L. Metzger did not report any details regarding the specifics of the landfills. Concentrations of specific compounds can be found in Appendix A.

Metzger also summarized the work of Breidenich (2003) who investigated the presence of several drugs in the leachate from five active municipal landfills in Germany. Of the twelve pharmaceuticals investigated, large concentrations (5-10 ìg/L) of clofibric acid, ibuprofen, carbamazepine, and phenacetin were found in the leachates. It is assumed that some of the landfills were lined as some were equipped with leachate treatment systems. Carbamazepine, clofibric acid, ibuprofen and diclofenac were also detected in groundwater down gradient of a closed landfill at concentrations ranging from 0.19 to 2.1 ìg/L. Concentrations for specific compounds can be found in Appendix A.

Fate of Pharmaceuticals in Landfill Leachate

Tischler/Kocurek (2007) prepared a report for the Pharmaceutical Research and Manufacturers of America, estimating the potential for release of 23 active pharmaceutical ingredients (APIs) to surface waters through disposal in Subtitle D municipal solid waste landfills (***i.e.***, those with low-permeability liners and leachate collection and/or treatment systems). Using reported pharmaceutical sales and estimates of the fraction of sold drugs disposed of in landfills (5-15%), municipal solid waste production, leachate production rates, compound specific partitioning coefficients, rates of anaerobic degradation and hydrolysis in landfills, and fractional removal of the APIs in leachate treatment systems (assumed to be equivalent to secondary wastewater treatment) the authors estimated the annual load of each API to surface water. The calculated mass loadings were compared with the loads of APIs released to surface waters through patient use via wastewater treatment plant effluent. Literature estimates of the loss by human metabolism and the degradation during conventional wastewater treatment were used in that calculation.

Not surprisingly, APIs with high sales and low partitioning coefficients had the highest potential release rates in landfill leachate. Despite several conservative estimates (e.g., disposal of drugs free of their packaging, leachate rates based on high average precipitation, and no assumed leachate recirculation or other operation to promote degradation), the average contribution of landfill leachate to the total load of all APIs to surface water was predicted to range from 0.21 to 0.78%. In other words, only a fraction of one percent of all APIs discharged to surface water was predicted to originate from drugs disposed of in municipal solid waste landfills. It should be noted that the predicted contribution of some individual APIs were considerably higher than the aggregate values reported above. Examples of APIs with high relative percentages

were albuterol sulfate (3-9%), doxycycline (2-6%), enalaprilat (7-19%), ibuprofen (4-10%), and norfloxacin (9-22%). In these cases, landfill disposal resulted in a higher percentage of the total load because the compounds had low partitioning coefficients and a large fraction of many of these compounds are metabolized, reducing the load to surface water via the patient use pathway.

The theoretical prediction that pharmaceuticals in leachate from municipal solid waste landfills accounts only for a small fraction of the total load of pharmaceuticals to a wastewater treatment plant (assuming that the leachate is disposed of to a sanitary sewer system) has been confirmed in one instance. Although specific percentages were not given, Schneider *et al.* (2004) reported that the contribution of landfill leachate to the total pharmaceutical load at a municipal wastewater treatment plant was small. Further evaluation of the results of the Tischler/Kocurek report can be accomplished by comparing the theoretical leachate concentrations presented in the report with field measurements from the studies cited above. Unfortunately, the only API predicted in the report and measured in the field is ibuprofen. The Tischler/Kocurek report predicts ibuprofen concentrations ranging from 43 to 130 mg/L in landfill leachate while actual field measurements ranged from 4 to 21 ìg/L (Paxeus, 2000; Schneider *et al.*, 2001; Breidenich, 2003; Schneider *et al.*, 2004). This comparison is further evidence that the estimates made in the Tischler/Kocurek report are indeed conservative. Nevertheless, active pharmaceutical compounds disposed of via municipal solid waste landfills are expected to contribute to the total load of those compounds to surface waters, if only at a small percentage of the total load including the patient use pathway.

Finally, the Tischler/Kocurek report indicates that the potential for release of pharmaceutical compounds from Subtitle D landfills to the underlying groundwater are negligible, based on the EPA's estimates of liner integrity and estimated lifetime. However, failure of landfill liners have been reported (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004). Furthermore, the literature cited above has also shown that disposal of pharmaceutical compounds to unlined landfills has occurred in the past and poses a substantial risk to the underlying groundwater.

Discussion

It is clear from the available literature that a variety of pharmaceutical compounds are being detected in the leachate collected in lined landfills and in groundwater contaminated by seepage from unlined landfills. In one instance, groundwater was contaminated by a leaking lined landfill (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004). Concentrations of a wide variety of prescription and non-prescription drugs in the leachate and contaminated groundwater have been found to range from less than 1 ng/L to approximately 18 mg/L (see Appendix A). Among the most commonly detected pharmaceuticals were the analgesics ibuprofen (up to 20.7 ìg/L in leachate, up to 0.19 ìg/L in groundwater) and propyphenazone (up to 120 ìg/L in leachate, up to 4 mg/L in groundwater) and clofibric acid, an environmental metabolite of a blood lipid regulator (up to 10 ìg/L in leachate, up to 1.3 ìg/L in groundwater).

The context for this report is the disposal of unused/unwanted drugs to solid waste landfills. As such, it is important to examine the potential source of the drugs quantified in these studies. In a few of the studies cited above, landfills received large quantities of hospital waste (Eckel *et al.*, 1993) or waste from pharmaceutical production (Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001). The highest concentrations (i.e., greater than approximately 100 ìg/L) of pharmaceutical compounds found in the groundwater down gradient of these unlined landfills is likely attributable to the large loads of pharmaceutical waste, rather than the disposal of unused/unwanted drugs. However, these studies do demonstrate the mobility and persistence of certain classes of pharmaceutical compounds in landfill, soil and groundwater environments.

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In addition to landfills receiving large quantities of pharmaceutical waste, some of the sites were noted to have received sludge from municipal wastewater treatment plants (Paxeus, 2000). It is possible that some of the pharmaceutical compounds present in the leachate originated from that sludge via municipal wastewater treatment, rather than the disposal of unwanted/unused drugs directly to the landfill. Although the earliest detections of pharmaceutical compounds in landfill leachates and contaminated groundwaters were from sites receiving large quantities of pharmaceutical waste, more recent studies, focusing on landfills receiving primarily commercial and household waste have also revealed the presence of pharmaceutical compounds in landfill leachate.

Lined vs. Unlined Landfills

In only one documented instance has groundwater been contaminated by a lined landfill. In that case (Schwarzbauer *et al.*, 2002; Heim *et al.*, 2004), a known leak in the landfill liner was the source of the subsurface contamination. On the other hand, several unlined landfills have been shown to have contaminated the underlying groundwater with pharmaceutical compounds (Eckel *et al.*, 1993; Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001; Breidenich, 2003; Barnes *et al.*, 2004). Although lined landfills are successful at containing pharmaceutically active compounds, those compounds must be treated, either at a dedicated leachate treatment facility, or at a municipal wastewater treatment plant. Any compounds that remain after that treatment are discharged to the environment. The report by Tischler/Kocurek (2007) predicted the partitioning, degradation, and treatment of several pharmaceutical compounds in leachate from lined landfills. That analysis required a great number of assumptions and it is clear that improved understanding of the fate of pharmaceutical compounds in lined landfills and leachate treatment systems is necessary. A current study is underway at the University of Florida (Townshend, 2003), but no results have been published at this time.

Active vs. Closed Landfills

There does not appear to be any correlation between the presence or absence of pharmaceuticals and whether the landfill is active or closed. However, the majority of the closed landfills that were investigated were unlined (Eckel *et al.*, 1993; Holm *et al.*, 1995; Breidenich, 2003; Barnes *et al.*, 2004). In those cases, direct contamination of the groundwater with pharmaceutical compounds was the result. Clearly, disposal of pharmaceuticals to unlined landfills poses a significant risk.

Conclusions

A wide variety of pharmaceutical compounds have been detected in landfill leachate from lined landfills and in groundwater down gradient of unlined landfills. The presence or absence of pharmaceuticals does not appear to be correlated with the operating status of the landfill (active vs. closed). However, a larger number of closed landfills were unlined and therefore posed a greater risk of direct contamination of the groundwater. Neglecting the sites thought to be contaminated with hospital (Eckel *et al.*, 1993) or pharmaceutical production waste (Holm *et al.*, 1995; Ahel *et al.*, 1998; Ahel and Jelicic, 2001), concentrations of pharmaceutical compounds in leachate ranged from less than 10 ng/L to as high as 120 ìg/L. In contaminated groundwater, concentrations ranged from < 1 ng/L to as high as 140 ìg/L. Much higher concentrations (up to 18 mg/L) were found in groundwater contaminated by unlined landfills that had received pharmaceutical production waste.

The potential benefits of disposing pharmaceutical compounds to landfills are the partitioning of some pharmaceuticals to organic matter and biological or chemical degradation within the

landfill. However, the fraction of the pharmaceutical compounds that end up in the leachate must be removed prior to surface water discharge; some fractions of those compounds can escape treatment and end up in the environment. Theoretical predictions (Tischler/Kocurek, 2007) and field data (Schneider *et al.*, 2004) suggest that drugs disposed of in municipal solid waste landfills contribute only a small fraction (< 1%) of the total load of pharmaceutical compounds discharged to surface water via municipal wastewater treatment plants and landfill leachate treatment systems. However, for individual compounds, this percentage is estimated to be as high as 20%. Although the total load of pharmaceuticals to surface waters is predicted to be small, it is not zero. Furthermore, the likelihood that drugs disposed of in landfills will ultimately end up in surface water is compound specific.

These preliminary studies provide a starting point, but further research is necessary to more completely understand the transformation and ultimate fate of pharmaceutical compounds in landfill leachate. To date, only a few studies have examined the concentrations of pharmaceutical compounds in leachate from lined landfills (Paxeus, 2000; Schneider *et al.*, 2001; Schwarzbauer *et al.*, 2002; Breidenich, 2003; Heim *et al.*, 2004; Schneider *et al.*, 2004) and all of those studies focused on landfills in countries other than the U.S. Additional study in the U.S. is necessary to more fully evaluate the occurrence and fate of pharmaceuticals in landfill leachates and the potential implications of the White House Office of National Drug Control Policy's guidance directing consumers to dispose of unused pharmaceuticals in household trash.

References

Ahel, M. & Jelicic, I. (2001) Phenazone analgesics in soil and groundwater below a municipal solid waste landfill. in Daughton, C. G. & Jones-Lepp, T. L. (Eds.) ***Pharmaceuticals and Personal Care Products in the Environment: Scientific and Regulatory Issues.*** Washington, DC, American Chemical Society.

Ahel, M., Mikac, N., Cosovic, B., Prohic, E. & Soukup, V. (1998) The impact of contamination from a municipal solid waste landfill (Zagreb, Croatia) on underlying soil. ***Water Science and Technology,*** 37 (8), 203-210.

Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. & Barber, L. B. (2004) Pharmaceuticals and other organic waste water contaminants within a leachate plume downgradient of a municipal landfill. ***Ground Water Monitoring and Remediation,*** 24 (2), 119-126.

Bellante, L., Chiavola, A., D'aprile, L. & Polettini, A. (2003) Assessment of the environmental impacts from drug disposal. ***Proceedings of the 17th International Conference on Solid Waste Technology and Management,*** 224-230.

Bound, J. P. & Voulvoulis, N. (2005) Household disposal of pharmaceuticals as a pathway for aquatic contamination in the United Kingdom. ***Environmental Health Perspectives,*** 113 (12), 1705-1711.

Breidenich, N. (2003) Drugs in leachates. ***Stuttgarter Berichte zur Siedlungswasserwirtschaft,*** 173 (Organische Spurenstoffe im Wasser: Kleine Konzentrationen--Grosse Wirkung?), 25-35.

Eckel, W. P., Ross, B. & Isensee, R. K. (1993) Pentobarbital found in ground water. ***Ground Water,*** 31 (5), 801-804.

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Heberer, T. (2002) Occurrence, fate, and removal of pharmaceutical residues in the aquatic environment: a review of recent research data. ***Toxicology Letters,*** 131 (1-2), 5-17.

Heim, S., Schwarzbauer, J. & Littke, R. (2004) Monitoring of waste deposit derived groundwater contamination with organic tracers. ***Environmental Chemistry Letters,*** 2 (1), 21-25.

Holm, J. V., Ruegge, K., Bjerg, P. L. & Christensen, T. H. (1995) Occurrence and distribution of pharmaceutical organic compounds in the groundwater downgradient of a landfill (Grindsted, Denmark). ***Environmental Science and Technology,*** 29 (5), 1415-20.

Jones, O. A. H., Voulvoulis, N. & Lester, J. N. (2005) Human pharmaceuticals in wastewater treatment processes. ***Critical Reviews in Environmental Science and Technology,*** 35 (4), 401-427.

Metzger, J. W. (2004) Drugs in municipal landfills and landfill leachates. ***Pharmaceuticals in the Environment (2nd Edition),*** 133-137.

ONDCP (2007) Proper Disposal of Prescription Drugs ***Drug Facts.*** Last updated: 20 March 2007. ONDCP. accessed: 8 August 2007. <http://www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html>

Paxeus, N. (2000) Organic compounds in municipal landfill leachates. ***Water Science and Technology,*** 42 (7-8), 323-333.

Schneider, C., Kuch, B., Braun, M. & Metzger, J. W. (2004) Pharmaceuticals in landfill leachates and receiving WWTP influents (Poster). ***14th Annual Meeting of SEATAC Europe.*** Prague.

Schneider, C., Mohle, E., Stenz, G., Kraus, P. & Metzger, J. W. (2001) Arzneimittel in Siedlungsabfallen und in Deponiesikerwassern. ***Mull and Abfall,*** 33 (6), 362-369.

Schwarzbauer, J., Heim, S., Brinker, S. & Littke, R. (2002) Occurrence and alteration of organic contaminants in seepage and leakage water from a waste deposit landfill. ***Water Research,*** 36 2275-2287.

Slack, R. J., Gronow, J. R. & Voulvoulis, N. (2005) Household hazardous waste in municipal landfills: contaminants in leachate. ***Science of the Total Environment,*** 337 (1-3), 119-137.

Tischler/Kocurek (2007) Potential releases of unused medicines in subtitle D landfill leachate. prepared for Pharmaceutical Research and Manufacturers of America.

Townshend, T. G. (2003) Determination of Selected Pharmaceutical Compounds and their Fate in Modern Lined Landfills ***Soil and Hazardous Waste Studies.*** Last updated: 6 September 2006. University of Florida. accessed: 15 August 2007. <http://www.ees.ufl.edu/homepp/townsend/Research/Pharm/default.asp>

USEPA (2007) ***Pharmaceuticals and Personal Care Products.*** Last updated: 12 June 2007. USEPA. accessed: 15 August 2007. <http://www.epa.gov/ppcp/>

APPENDIX A – SUMMARY OF DATA FROM LITERATURE REVIEW

Drug Classification	Compound	Concentration (i g/L)[1]		Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
		Leachate	Groundwater					
analgesic, antiphlogistic, anti-inflammatory, antipyretic	aminopyrine	0.06-16	<0.05-36	N	Y	PPW	Ahel and Jelicic (2001)	solid waste (0.005-0.02 mg/kg) soil (0.003-0.007 mg/kg)
	antipyrine	<0.05		N	Y	PPW	Ahel and Jelicic (2001)	
	diclofenac	1.8			Y*		Schneider et al. (2001)	data from Metzger (2004)
			0.26	N*	N		Breidenich (2003)	data from Metzger (2004)
		3.19		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.183		Y*	Y	HW	Schneider et al. (2004)	median concentration
	dimethylamionphenazone	4.764		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.668		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ibuprofen	8			Y		Paxeus (2000)	no HW at this landfill according to the article
		20.7			Y*		Schneider et al. (2001)	data from Metzger (2004)
		N.Q.	N.Q.	Y	Y		Schwarzbauer et al. (2002)	
		9.5			Y		Breidenich (2003)	data from Metzger (2004)
			0.19	N*	N		Breidenich (2003)	data from Metzger (2004)
			N.D.	Y	Y		Heim et al. (2004)	
			<0.005		Y		Heim et al. (2004)	groundwater discharge to surface water
		9.362		Y*	Y	HW	Schneider et al. (2004)	median concentration
		4.894		Y*	Y	HW	Schneider et al. (2004)	median concentration
	indomethacine	1.6			Y*		Schneider et al. (2001)	data from Metzger (2004)
		0.017		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.141		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ketoprofen	0.697		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.438		Y*	Y	HW	Schneider et al. (2004)	median concentration
	naproxen	0.445		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.288		Y*	Y	HW	Schneider et al. (2004)	median concentration
	phenacetin	4.7			Y		Breidenich (2003)	data from Metzger (2004)
	piroxicam	0.481		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.931		Y*	Y	HW	Schneider et al. (2004)	median concentration
	phenazone	37			Y		Paxeus (2000)	
		5.507		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.761		Y*	Y	HW	Schneider et al. (2004)	median concentration
	piroxicam	0.481		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.931		Y*	Y	HW	Schneider et al. (2004)	median concentration
	propyphenazone		<10-4000	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
				N	Y	PPW	Ahel et al. (1998)	<0.01-0.1 mg/kg (soil); 0.1-10 mg/kg (solid waste)
		1.1			Y		Paxeus (2000)	
		49			N		Paxeus (2000)	
		3.7-60	5-50	N	Y	PPW	Ahel and Jelicic (2001)	solid waste (0.05-22 mg/kg) soil (0.003-2.9 mg/kg)
		110-120	140	Y	Y		Schwarzbauer et al. (2002)	
			<0.001-1.4	Y	Y		Heim et al. (2004)	
			0.002-0.1	Y	Y		Heim et al. (2004)	groundwater discharge to surfacewater
		9.173		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.455		Y*	Y	HW	Schneider et al. (2004)	median concentration
antibiotic	lincomycin		<0.05-0.10	N	N		Barnes et al. (2004)	
	sulfadiazine		<20-1160	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfadimidine		<20-900	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfaguanidine		<20-1600	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfametizole		<20-330	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfanilamide		<20-300	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	sulfanilic acid		<20-10440	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient

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Drug Classification	Compound	Concentration (i g/L)[1] Leachate	Groundwater	Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
anticonvulsant, antiepileptic	carbamazepine	5.2			Y		Breidenich (2003)	data from Metzger (2004)
			2.1	N*	N		Breidenich (2003)	data from Metzger (2004)
		1.415		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.202		Y*	Y	HW	Schneider et al. (2004)	median concentration
	phensuximide		N.Q.	N	N	MW	Eckel et al. (1993)	
	primidone	3			Y*		Schneider et al. (2001)	data from Metzger (2004)
		5.011		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.002		Y*	Y	HW	Schneider et al. (2004)	median concentration
	valproic acid	0.205		Y*	Y	HW	Schneider et al. (2004)	median concentration
	valproic acid	0.122		Y*	Y	HW	Schneider et al. (2004)	median concentration
anti-foaming agent	tris(2-methylpropyl) phosphate		<1-80	N	N	PPW	Holm et al. (1995)	used in pharmaceutical production
antineoplastic	cyclophosphamide	0.192		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.097		Y*	Y	HW	Schneider et al. (2004)	median concentration
	ifosfamide	0.042		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.032		Y*	Y	HW	Schneider et al. (2004)	median concentration
antitussiva	dihydrocodeine	0.101		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.014		Y*	Y	HW	Schneider et al. (2004)	median concentration
barbituate	5,5-diallylbarbituric acid		<10-205	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
beta-blocker	atenolol	0.044		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.034		Y*	Y	HW	Schneider et al. (2004)	median concentration
	metroprolol	0.031		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.024		Y*	Y	HW	Schneider et al. (2004)	median concentration
	propranolol	0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
bronchiodilator	clenbuterol	<0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
		<0.01		Y*	Y	HW	Schneider et al. (2004)	median concentration
byproducts of sulfonamide production	aniline		<10-1100	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	o-chloroaniline		<10-110	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
	p-chloroaniline		<10-50	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
hypnotic/sedative	pentobarbital		1	N	N	MW	Eckel et al. (1993)	
intermediate in production of meprobamate	2-methyl-2-n-propyl-1,3-propanediol		<10-18000	N	N	PPW	Holm et al. (1995)	depth = 5.5-10 m; distance = 0-260 m down gradient
lipid regulator	clofibric acid (a metabolite)	2.9			Y*		Schneider et al. (2001)	data from Metzger (2004)
		N.Q.	N.Q.	Y	Y		Schwarzbauer et al. (2002)	
		10			Y		Breidenich (2003)	data from Metzger (2004)
			1.3	N*	N		Breidenich (2003)	data from Metzger (2004)
			<0.005-1.1	Y	Y		Heim et al. (2004)	
			<0.005-0.055	Y	Y		Heim et al. (2004)	groundwater discharge to surfacewater
		2.658		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.879		Y*	Y	HW	Schneider et al. (2004)	median concentration
	bezafibrate	1.353		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.773		Y*	Y	HW	Schneider et al. (2004)	median concentration
metabolite of nicotine	cotinine		<0.05-0.13	N	N		Barnes et al. (2004)	

Drug Classification	Compound	Concentration (ï g/L)[1] Leachate	Groundwater	Liner[2]	Active[3]	Source[4]	Citation[5]	Notes
phosphodiesterase inhibitor	pentoxyfylline	2.1			Y*		Schneider et al. (2001)	data from Metzger (2004)
production of vitamin C	isopropylidene carbohydrate deriv.			N	Y	PPW	Ahel et al (1998)	<0.1-1 mg/kg (soil) <0.1->10 mg/kg (solid waste)
psychiatric drug	diazepam	0.453		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.192		Y*	Y	HW	Schneider et al. (2004)	median concentration
sedative	meprobamate		N.Q.	N	N	MW	Eckel et al (1993)	
			N.Q.	N	N	PPW	Holm et al (1995)	anecdotal evidence
vasodilator	pentoxifylline	2.875		Y*	Y	HW	Schneider et al. (2004)	median concentration
		1.116		Y*	Y	HW	Schneider et al. (2004)	median concentration
x-ray contrast media	amidotrizoic acid	0.242		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iomeprol	0.092		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.042		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iopamidol	2.485		Y*	Y	HW	Schneider et al. (2004)	median concentration
		2.944		Y*	Y	HW	Schneider et al. (2004)	median concentration
	iopromide	0.199		Y*	Y	HW	Schneider et al. (2004)	median concentration
		0.236		Y*	Y	HW	Schneider et al. (2004)	median concentration

[1] N.D. = not detected; N.Q.= detected but not quantified.

[2] Y indicates that the landfill was lined, N indicates that the landfill was unlined. Entries with an asterisk were inferred. Blank entries indicate no data.

[3] Y indicates an active landfill; N indicates a closed landfill. Entries with an asterisk were inferred. Blank entries indicate no data.

[4] Column indicates the likely source of the pharmaceutical in the landfill. HW = household waste; MW = medical waste; PPW = pharmaceutical production waste.

[5] When more than one entry from the same reference for the same chemical, values refer to different landfills.

10.4 Appendix C: Potential Grant Options for Year 1 Funding

10.4.1 STATE

Program: Nonpoint Source Pollution 319 Grants

- Agency: DEQ
- Overview: Nonpoint source water quality and watershed enhancement projects that address the priorities in the Oregon Water Quality Nonpoint Source Management Plan.
- Award: Approximately $2.7M available each year
- Link: *http://www.deq.state.or.us/bc/grants.htm*

Program: Solid Waste Grants

- Agency: DEQ
- Overview: Solid waste management and waste reduction programs
- Award: Approximately $250,000 available each year
- Link: *http://www.deq.state.or.us/lq/sw/grants/index.htm*

Program: Opportunities for learning about watershed concepts

- Agency: Oregon Watershed Enhancement Board (OWEB)
- Overview: Must be used for education and outreach materials
- Award: Approximately $500,000 total available each year
- Link: *http://www.oregon.gov/OWEB/GRANTS/education_grants.shtml*

10.4.2 FEDERAL

Program: Pollution Prevention (P2)Grant Program

- Agency: EPA
- Overview: The grant program provides matching funds to state and tribal programs to support P2 activities across all environmental media and to develop state programs.
- Award: None listed
- Link: *http://www.epa.gov/oppt/p2home/pubs/grants/ppis/2007fpp2grant.htm*

Program: Source Reduction Assistance Grants: Program

- Agency: EPA
- Overview: To fund projects that support pollution prevention/source reduction and/or resource conservation activities.
- Award: Up to $163,000 per region
- Link: *http://www.epa.gov/oppt/p2home/pubs/grants/srap06.htm*

Program: General Matching Grants Program

- Agency: National Fish and Wildlife Foundation
- Overview: Grants to projects that address priority actions promoting fish and wildlife conservation and the habitats on which they depend, work proactively to involve other conservation and community interests
- Award: Range from $25,000-$250,000
- Link: http://www.nfwf.org/guidelines.cfm

Drug Free Communities Support Program

- Agency: Substance Abuse & Mental Health Services Administration
- Overview: Program should achieve two major goals: Reduce substance abuse among youth and, over time, among adults by addressing the factors in a community that increase the risk of substance abuse and promoting the factors that minimize the risk of substance abuse.
- Award: $100,000
- Link: http://www.samhsa.gov/grants06/RFA/sp_06_003_dfc.aspx

Strategic Prevention Framework State Incentive Grant Program

- Agency: Substance Abuse & Mental Health Services Administration
- Overview: To build prevention capacity and infrastructure at the State/Tribal and community levels.
- Award: Up to $2.3 million a year
- Link: http://www.samhsa.gov/Grants06/RFA/sp06_002_sig.aspx

Program: Healthy Communities Grant Program Synopsis

- Agency: EPA
- Overview: Funds projects that: Target resources to benefit communities at risk and sensitive populations, Assess, understand, and reduce environmental and human health risks, and Achieve measurable environmental and human health benefits.
- Award: Up to $35,000
- Link: http://www.grants.gov/search/search.do?oppId=12476&mode=VIEW

Program: Pollution Prevention Grants Program

- Agency: EPA
- Overview: Grant dollars are targeted at State and Tribal technical assistance programs to assist businesses and industries in identifying better environmental strategies and solutions for reducing or eliminating waste at the source across all environmental media.
- Award: Up to $200,000
- Link: http://www.grants.gov/search/search.do?oppId=12426&mode=VIEW

Program: Prescription Drug Abuse

- Agency: National Institutes of Health
- Overview: to address this issue are encouraged across a broad range of experimental approaches including basic, clinical, epidemiological, prevention, and treatment studies.
- Award: Funds available over $500,000 per project per year
- Link: http://grants.nih.gov/grants/guide/pa-files/PA-04-110.html

Program: Community Action For a Renewed Environment (CARE) Program

- Agency: EPA
- Overview: The CARE program helps communities form collaborative partnerships, develop a comprehensive understanding of the many sources of risk from toxics and pollutants, set priorities, and identify and carryout projects to reduce risks through collaborative action at the local levels
- Award: $2.7 million nationally
- Link: *http://www.epa.gov/CARE*

10.4.3 PRIVATE

The Brainerd Foundation

- Overview: Program grants may cover costs associated with a specific project of an organization, or be "general support" focused, meaning the grant may be applied to any portion of an organization's budget. Designated program areas: conservation policy, placed-based conservation and conservation capacity.
- Award: Usually range from $20,000 - $35,000 over two years
- Link: *http://www.brainerd.org/grants/intro.php*

Bullitt Foundation

- Projects to protect, restore, and maintain the natural physical environment of the Pacific Northwest for present and future generations.
- Link: *http://www.bullitt.org/grants*

Pharmaceutical Trade Organization

- As a NGO they are allowed to apply as well as give for grants

M.J. Murdock Charitable Trust

- The Trust makes grants primarily in five states of the Pacific Northwest in the areas of Interest of: Education, Scientific Research, Arts and Culture, Health and Human Services
- Link: *http://www.murdock-trust.org/*

Meyer Memorial Trust

- Overview: General Purpose Grants support projects related to arts and humanities, education, health, social welfare, community development, the environment and a variety of other activities.
- Awards: Up to $200,000 a year
- Link: *http://www.mmt.org/grants_programs/gpg/*

Oregon Community Foundation

- Overview: OCF provides a variety of charitable fund and gift options to help Oregonians make a difference.
- Link: *http://www.ocf1.org/grant_programs/grant_programs.html*

11 References

Ball, Judy K, Eric Johnson, and Elizabeth Foley. 2007. ***Drug Abuse Warning Network, 2005: National Estimates of Drug Related Emergency Department Visits*** [Report]. Office of Applied Studies 2005 [cited April 2007]. Available from http://dawninfo.samhsa.gov/files/DAWN-ED-2005-Web.pdf.

Barber, Larry B., Sheila F. Murphy, Philip L. Verplanck, Mark W. Sandstrom, Howard E. Taylor, and Edward T. Furlong. 2006. Chemical Loading into Surface Water along a Hydrological, Biogeochemical, and Land Use Gradient: A Holistic Watershed Approach. ***Environmental Science and Technology*** 40 (2):475-486.

Barnes, KK, SC Christenson, DW Kolpin, MJ Focazio, ET Furlong, SD Zaugg, MT Meyer, and LB Barber. 2004. Pharmaceuticals and other organic waste water contaminants within a leachate plume downgradient of a municipal landfill ***Ground Water Monitoring and Remediation*** 24 (2):119-126.

Bateman, Brenda, Ralph Thonstad, and Daniel Danicic. 2007. Conflicting Public Policies: Why is it so difficult to keep pharmaceuticals out of the water? ***Water Resources Impact*** 9 (3):18-21.

Bay Area Pollution Prevention Group. 2006. Report on the San Francisco Bay Area's Safe Medicine Disposal Days.

Bound, Jonathan P., and Nikolaos Voulvoulis. 2005. Household Disposal of Pharmaceuticals as a Pathway for Aquatic Contamination in the United Kingdom. ***Environmental Health Perspectives*** 113 (12):1705-1711.

Buzby, Mary E. 2007. ***Pharmaceuticals in the Environment: PhRMA PIE Perspective*** [Presentation], May 22 2007 [cited May 30 2007]. Available from http://www.dtsc.ca.gov/AssessingRisk/PPCP/upload/04_Buzby.pdf.

Carter, Thomas W. 2006. ***Safe Drinking Water Act and Its Interpretation.*** First ed. New York: Nova Science Publishers.

Christensen, F. M. 1998. Pharmaceuticals in the Environment—A Human Risk? ***Regulatory Toxicology and Pharmacology*** 28 (3):212-221.

Clark County Public Works. 2006. Medical Waste -- Unwanted Medications, edited by C. C. P. Works.

Clark County Solid Waste. 2006. ***Unwanted Medications Take Back Program.*** Portland, OR. Power Point.

Cocke, William. 2006. ***Male Fish Producing Eggs in Potomac River,*** November 3 2004 [cited October 10 2006]. Available from http://news.nationalgeographic.com/news/2004/11/1103_041103_potomac_fish.html#main.

Colliver, J D, L A Kroutil, L Da, and J C Gfroerer. 2007. ***Misuse of prescription drugs: Data from the 2002, 2003, and 2004 National Surveys on Drug Use and Health*** [Report]. Office of Applied Studies 2006 [cited June 3 2007]. Available from http://oas.samhsa.gov/prescription/toc.htm.

Daughton, C. G. 2004. Ground Water Recharge and Chemical Contaminants. ***Ground Water Monitoring and Remediation*** 24 (2):127-138.

Daughton, C. G., and T. A. Ternes. 1999. Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change? ***Environmental Health Perspectives*** 107 (Supplement 6): 907-938.

Health Resources and Services Administration. 2007. ***Poisoning in the United States*** [cited Feb 3, 2007]. Available from http://www.hrsa.gov/poisoncontrol/default.htm.

Henry F. Kaiser Family Foundation. 2007. ***State Health Facts: Oregon Prescription Drugs*** [Report], March 25 2007 [cited 2007]. Available from http://statehealthfacts.org/cgi-bin/healthfacts.cgi?action=profile&ar...egon&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs.

Hinkle, Stephen R., Rodney J. Weick, Jill M. Johnson, Jeffery D. Cahill, Steven G. Smith, and Barbara J. Rich. 2005. Organic Wastewater Compounds, Pharmaceuticals, and Coliphage in Ground Water Receiving Discharge from Onsite Wastewater Treatment Systems near La Pine, Oregon: Occurrence and Implications for Transport: USGS.

Jackson, Jen. 2007. ***Pharmaceuticals: an "Emerging" Contaminant*** [Presentation], November 13 2006 [cited June 7 2007]. Available from http://www.oracwa.org/files/news/179/Pharmaceuticals--Jen-Jackson.pdf.

Kolpin, D., E. Furlong, M. Meyer, E.M. Thurman, S. Zaugg, L. Barber, and H. Buxton. 2002. Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance. ***Environmental Science Technology*** 36 (6):1202 - 1211.

Kostich, Mitch, and Jim Lazorchak. 2006. ***An informatic approach to estimating ecological risks posed by pharmaceutical use: Human prescription pharmaceuticals***. Power Point.

Kuspis, D A, and E P Krenzelok. 1996. What happens to expired medications? A survey of community medication disposal. ***Veterinary and Human Toxicology*** 38:48-49.

Mannina, George J. 2006. Medicines and the Environment: Legal and Regulatory Storms Ahead? ***Washington Legal Foundation*** 21 (11):4.

Nagler, James J., Jerry Bouma, Gary H. Thorgaard, and Dennis D. Dauble. 2001. High Incidence of a Male-Specific Genetic Marker in Phenotypic Female Chinook Salmon from the Columbia River. Environmental Health Perspectives 109 (1):67-69.

National Archives and Records Administration. 2006. ***Title 21: Food and Drugs*** [Statute], January 8 2004 [cited October 3 2006]. Available from http://www.access.gpo.gov/uscode/title21/chapter13_subchapteri_.html.

National Association of Chain Drug Stores. 2007. ***Rx Sales 2006*** [Report], June 9 2007 [cited June 12 2007]. Available from http://www.nacds.org/wmspage.cfm?parm1=507.

NDWAC. 2007. ***National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency*** [Report]. National Drinking Water Advisory Council, May 18 2004 [cited June 3 2007]. Available from *http://www.epa.gov/safewater/ndwac/pdfs/report_ccl_ndwac_07-06-04.pdf*.

NEMU. 2007. ***Thermostat Recycling Corporation*** [Information] 2007 [cited June 9 2007]. Available from *http://www.nema.org/gov/ehs/trc/*.

Office of Diversion Control. ***Controlled Substances in Alphabetical Order*** 2006 [cited. Available from *http://www.deadiversion.usdoj.gov/schedules/alpha/alphabetical.htm*.

Oregon Board of Pharmacy. 2007. OAR 855-041-0080 Returned Drugs and Devices.

Oregon Department of Human Services. 2004. 24 Hour Residential Services for Children and Adults with Developmental Disabilities.

Oregon Poison Center. 2006. ***2004 Annual Report*** [Annual Report]. Oregon Poison Center 2004 [cited October 3 2006]. Available from *http://www.ohsu.edu/poison/about/annualReports.htm*.

Oregon Progress Board. 2007. ***Benchmark Report to the People of Oregon*** [Report], April 2007 [cited May 30 2007]. Available from *http://benchmarks.oregon.gov/*.

Population Research Center. 2007. ***Certified Population Estimates for Oregon and Its Counties*** [Report]. Portland State University, December 15 2006 [cited January 15 2007]. Available from *http://www.pdx.edu/prc*.

Post Consumer Pharmaceutical Stewardship Association. 2006. Medications Return Program Report: January 1, 2005 - December 31, 2005.

Raloff, J. 2004. Contraceptive Ring Could Pose Risks After Its Disposal. ***Science News***.

RBRC. 2007. ***Call2Recycle*** [Information Piece] 2006 [cited June 9 2007]. Available from *http://www.rbrc.org/call2recycle/*.

State of Maine 122nd Legislature. 2006. ***Final Report of the Maine Drug Return Implementation Group*** State of Maine 122nd Legislature, March 8 2005 [cited October 3 2006]. Available from *http://www.maine.gov/legis/opla/drugrpt.pdf*.

State of Maine Legislature. 2006. ***An Act To Encourage the Proper Disposal of Expired Pharmaceuticals*** [Legislative Bill], April 16 2004 [cited October 3 2006]. Available from *http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280012218&LD=1826&Type=3&SessionID=5*.

Substance Abuse and Mental Health Services Administration. 2007. ***Federal Report Shows New Nonmedical Users of Prescription Pain Relievers Outnumbered New Marijuana Users between 2002 and 2004***, November 2 2006 [cited January 3 2007]. Available from *http://www.samhsa.gov/newsroom/advisories/061102misuse5701.aspx*.

U.S. Department of Health and Human Services. 2006. ***Medical Privacy - National Standards to Protect the Privacy of Personal Health Information*** [Regulation]. Office for Civil Rights, May 16 2006 [cited September 30 2006]. Available from *http://www.hhs.gov/ocr/hipaa/finalreg.html*.

_____.2005. 2005 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration. Available from http://oas.samhsa.gov

U.S. Drug Enforcement Administration. 2006. *21 USC Sec. 822* [Code] 2002 [cited October 10 2006]. Available from http://www.usdoj.gov/dea/pubs/csa/822.htm.

U.S. Environmental Protection Agency. *Pharmaceuticals and Personal Care Products (PPCPs) as Environmental Pollutants* 2006 [cited. Available from http://www.epa.gov/nerlesd1/chemistry/pharma.

———. *2006. RCRA Online* 2006 [cited September 30 2006]. Available from http://www.epa.gov/rcraonline/RCRA.

U.S. Fish & Wildlife Service, and American Pharmacists Association. 2007. *Improper Disposal of Unused Medications Sparks Creation of New Awareness Program* [Press Release], March 17 2007 [cited April 1 2007]. Available from http://www.fws.gov/southeast/news/2007/r07-050.html.

U.S. Postal Service. 2006. *Mailing Standards of the United States Postal Service Domestic Mail Manual* 2006 [cited September 30 2006]. Available from http://pe.usps.com/text/dmm300/pub268.htm.